Int Urogynecol J (2011) 22 (Suppl 1):S1–S195
DOI 10.1007/s00192-011-1434-z

Oral Presentations

36th Annual IUGA Meeting, Lisbon, Portugal, 28 June - 2 July 2011

Presentation Number: 001

A SYSTEMATIC REVIEW AND META-ANALYSIS OF SINGLE-INCISION MINI-SLINGS VERSUS STANDARD MID-URETHRAL SLINGS IN SURGICAL MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE

P. MADHUVRATA[1], J. FORD[2], C. P. LIM[3], M. ABDEL FATTAH[2];
[1]Sheffield Teaching Hosp., Sheffield, United Kingdom, [2]Univ. of Aberdeen, Aberdeen, United Kingdom, [3]Aberdeen Royal Infirmary, Aberdeen, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To assess the current evidence of effectiveness and safety of Single Incision Mini-Slings (SIMS) compared to Standard Mid-Urethral Slings (SMUS): retropubic (RT-TVT) and transobturator (TO-TVT) tension-free vaginal tapes in the management of female stress urinary incontinence (SUI).

Background:
Single Incision Mini-Slings (SIMS) were introduced in 2006 for the treatment of female SUI; aiming to reduce post-operative pain, recovery time and peri-operative complications by a single-incision procedure while maintaining equivalent efficacy to SMUS.

Methods:
A prospective peer-reviewed protocol for this review was prepared a priori; a meta-analysis of all published RCTs comparing SIMS and SMUS in accordance with PRISMA. Literature search was performed up to January 2011.Two authors independently extracted data.Data was analysed using Rev-Man 5. Meta-analysis was performed using the random effects model and heterogeneity calculated using I^2 estimate. Primary outcomes were patient-reported and objective cure rates. Secondary outcomes included quality of life, sexual function, surgical complications, repeat continence surgery and economic measures.

Results:
Nine studies were included; two comparing SIMS versus RT-TVT and seven versus TO-TVT. A total of 653 women with 6–12 months follow-up were analysed. The mean age (52.3 vs. 52.1 years), mean BMI (27.4 vs. 27.7) and mean parity (2.4 and 2.4) were comparable for SMUS vs. SIMS respectively.
SMUS were associated with significantly higher patient-reported and objective cure rates on the short term compared to SIMS (Risk Ratio [RR] 1.20 95%CI 1.01, 1.43 and RR 1.18, 95%CI 1.04, 1.34). Figure 1shows breakdown analysis of RT-TVT & TO-TVT vs. SIMS. These results were supported on sensitivity analysis when studies of unclear quality were excluded.
Compared to SMUS, SIMS were associated with significantly shorter operative time (weighted mean difference [WMD] 8.67 min 95%CI 0.02, 17.32) and significantly lower day-1 pain scores (WMD 1.74 95%CI 0.90, 2.58). Post-operative groin pain (RR 14.09, 95%CI 2.70, 73.52) was significantly higher with TO-TVT.
Repeat continence surgery (RR 0.15, 95%CI 0.05, 0.42), tape erosion (RR 0.26, 95%CI 0.10, 0.69) and *de novo* urgency incontinence (RR 0.48, 95%CI 0.23, 0.99) were significantly lower in the SMUS group compared to SIMS, however there was no significant difference in postoperative hospital stay (WMD 0.03 days 95%CI −0.11, 0.17).
There was no significant difference in the QoL scores between the groups (WMD −33.46, 95%CI −87.55, 20.62). No studies compared postoperative sexual function or cost to health services.

Conclusions:
SIMS are associated with significantly lower post-operative pain when compared to SMUS. However, they are associated with inferior patient-reported and objective cure rates on the short-term follow-up, as well as higher re-operation rates for stress urinary incontinence.
This meta-analysis confirms clinician concerns on efficacy of SIMS in treatment of female SUI; our results do not support routine use of SIMS in clinical practice.

Figure 1: Patient Reported Cure Rate

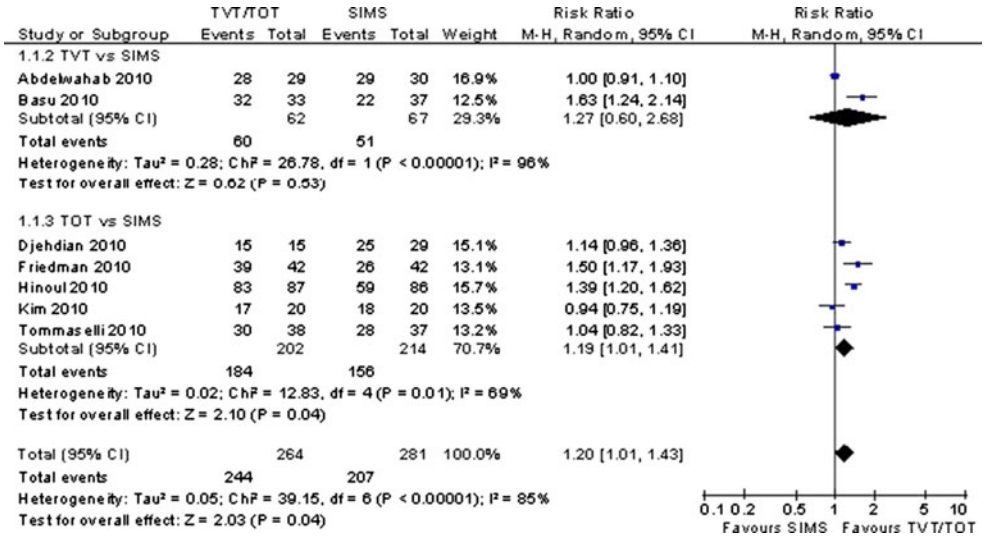
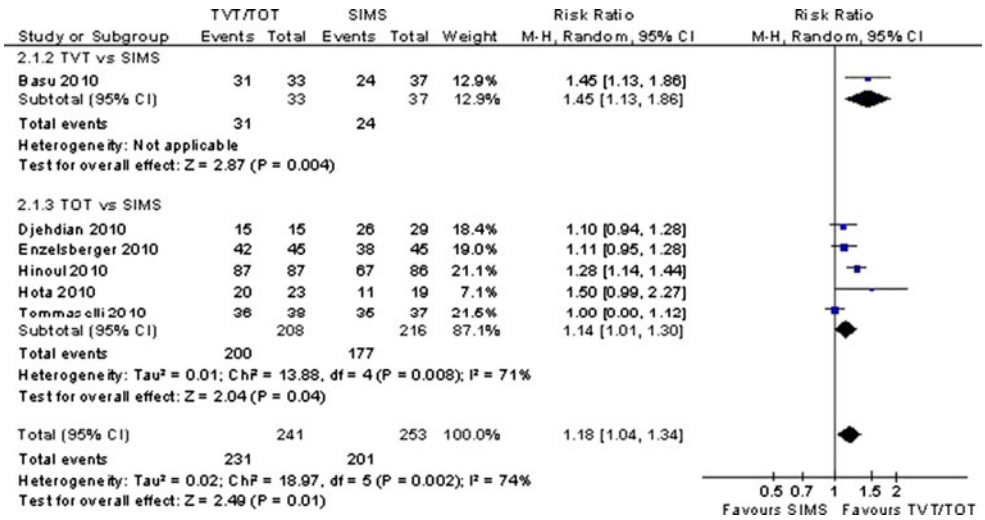


Figure 2: Objective Cure Rate



Presentation Number: 002

A BLINDED MULTI-CENTER RANDOMIZED TRIAL COMPARING TVT-SECUR "U" TO THE TENSION-FREE VAGINAL TAPE (TVT) FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

M. D. BARBER, Foundation For Female Health Awareness Study Group;
Cleveland Clinic, Cleveland, OH.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To compare the safety and efficacy of the TVT-SECUR placed in the "U" position to TVT in the treatment of stress urinary incontinence in patients with and without concurrent pelvic organ prolapse.

Background:
The TVT-SECUR is a single-incision "mini-sling" that can be implanted using a retropubic "U" approach or a transobturator-like "hammock" approach. A recent multicenter randomized trial found that both methods of TVT-SECUR provided comparable cure rates for female SUI. However, quality of life and treatment satisfaction favored the U method (1). To date, no clinical trials have compared the TVT-SECUR "U" to standard retropubic midurethral slings like the TVT.

Methods:
Women with urodynamic stress incontinence with and without concurrent pelvic organ prolapse were invited to participate in this clinical trial from seven U.S. medical centers. Subjects with detrusor overactivity or previous sling surgery were excluded. Subjects were randomized to receive TVT-SECUR or TVT on the

day of surgery. Randomization was stratified by clinical site and the presence or absence of pelvic organ prolapse beyond the hymen. TVTs were placed"tension-free" so that there was no contact between the sling and the urethra at placement. TVT-SECURs were implanted in the "U" position and, based on our initial experience, tensioned "tightly" so that the sling directly opposed the urethra such that a spacer could not be put between them. Two "sham" partial thickness suprapubic skin incisions were made in all TVT-SECUR subjects to mimic TVT incisions in order to blind the subjects and research nurses. A research nurse at each site who was masked to treatment assignment performed all postoperative visits and administered all questionnaires. At baseline, 6,12,18 and 24 months after surgery subjects completed the Incontinence Severity Index (ISI), the PFDI-20 and PFIQ-7. At the 12 and 24 month follow-up subjects completed a 3-day bladder diary. Postoperative pain was assessed using the Surgical Pain Scales daily for the first 2 weeks after surgery and again at 6 weeks. The primary outcome was assessed at 1 year and defined as "cure" of incontinence (ISI score of 0 ("dry") and absence of re-treatment for stress urinary incontinence during study follow-up). This trial is a non-inferiority study design. A sample size of 127 subjects per group provides 80% power to test the hypothesis that TVT-SECUR is not inferior to TVT by more than 15% using a two-group large-sample normal approximation test of proportions with a one-sided 0.05 significance level. Anticipating a 10% loss to follow-up and/or drop out rate over the period of the study, the total enrollment goal is 280.

Results:

Of 281 subjects enrolled, 263 underwent surgery and 261 returned for follow-up (93%). TVT-SECUR or TVT was performed alone in 119 (45%) while the remainder underwent additional surgical procedures. Subjects who received TVT were more likely to undergo concurrent hysterectomy (26% vs. 9%, p=.01) but no other differences in rates or types of concurrent surgery were noted. Mean operating time, blood loss and hospital stay were similar between groups. Subjects receiving TVT were more likely to have a bladder injury (6% vs. 1%, p=.046) but other intraoperative and postoperative complications were similar between groups. In spite of being tensioned tightly, the TVT-SECUR group was more likely to be discharged without use of a catheter than those in the TVT group (78.5% vs 63%, p=.008) and the median catheter duration was similar between groups (0 [range 0–14] vs. 0.5 [range 0–14] days). Prolonged voiding dysfunction, defined as need for catheterizatin >42 days or need for urethrolysis, was infrequent in both groups (1.7% vs 2.4%, p=.67). TVT-SECUR resulted in less pain for the first 3 postoperative days but no differences in pain scores were noted thereafter and duration of pain medication use was similar between groups. One year after surgery, the rate of cure was similar between treatment groups (TVT-SECUR 57% vs. TVT 60% [mean difference −3.0%; 95% Confidence Interval −14.9 to 9] however incontinence severity was greater in the TVT-SECUR group (mean ISI score + SD: 2.2+2.7 vs. 1.5+1.9, p=.015) resulting predominantly from a higher proportion of subjects with "severe" incontinence (ISI=8) postoperatively:16% vs. 5%, p=.026. Retreatment for stress incontinence occurred in 1.5% and 2.4% of subjects, respectively, p = .43. HRQOL improved significantly in both groups after surgery but postoperative IIQ scores favored TVT (p = .047).

Conclusions:

TVT-SECUR "U" is safe and results in similar cure rates to TVT one year after surgery, however postoperative incontinence severity is less with TVT.

References:

1. Eur Urol 2010 57:980–2

Presentation Number: 003

RANDOMIZED PROSPECTIVE TRIAL OF A COMPARISON OF THE EFFICACY OF TVT-O AND TVT SECUR SYSTEM IN THE TREATMENT OF STRESS URINARY INCONTINENT WOMEN - LONG-TERM RESULTS

J. MASATA, K. SVABIK, R. ELHADDAD, P. HUBKA, P. DRAHORADOVA, A. MARTAN;
Charles Univ., 1st Faculty of Med., Obstet. Gynecol. Dept., Prague 2, Czech Republic.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of this study was to compare the efficacy of, and the complications involved in, the use of TVT-O and TVT SECUR systems, H and U approach (TVT-S) in the treatment of stress urinary incontinent women.

Background:

In 1996 Ulmesten and Petros described the method of tension-free vaginal tape (TVT), which is minimally invasive and has a comparable effect to Buch colposuspension. Due to retropubic trajectory during the tape insertion, serious perioperative complications were described, including injury of the major vessels and bowel injury. In 2001 was described the placement of the tape via the transobturator route (outside-in). The next modification of transobturatory was the tape placement inside-out (2003). Tape surgical methods are at present considered the gold standard for surgical treatment of stress urinary incontinence, but they are associated with some complications. In an attempt to reduce further the invasive nature of the procedure and the rate of complications, a new generation of tension-free vaginal tapes has been introduced, known as minitapes. The first tape of this type was TVT-Secur (TVT-S). The firstly published short-term results were promising, and the data showed similar efficacy as retropubic or transobturatory tapes. Subsequent studies show lower efficacy than was expected, and several case reports describing serious bleeding after this procedure were published.

Methods:

Between January 2007 and November 2009 197 women with proven urodynamic stress urinary incontinence were included in this prospective randomized trial. For randomization the envelope technique was used. Before enrolment to the study all patient signed informed concern. Patients were randomized into three groups - TVT-O (68), TVT - S H approach (64) and in TVT-S U approach (65). Based on pre-study statistical calculations it was indicated that the required sample size in each group is 65 patients.All patients underwent complete urogynecological inves-

tigation before the procedure (clinical examination, urodynamics, ultrasound examination), and they filled in the ICIQ and iQol questionnaire. Surgery was only offered if conservative therapy was unsuccessful. Exclusion criteria were: predominant urge incontinence, urodynamic detrusor instability, previously failed anti-incontinence surgery, previous radiotherapy, postvoid residual volume (PVR) greater than100 ml, bladder capacity less than 300 ml, and, stage II, III, or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, planned concomitant surgery, age<18.The peri-operative complications were monitored. After the study the patients underwent a complete examination 3 months after surgery (the same examination as before the procedure). The next check-ups were provided 1 year and 2 years after surgery (or 3 years, of the 2-year check-up was omitted), and the investigation was same as at the 3-month check-up except for urodynamics. Postoperative follow-up was terminated if the result of surgery was evaluated as a failure and reoperation was offered.

Results:

There were no significant differences in age, body mass index, parity, or history of surgery for gynecological disorders among the study participants. Preoperative urodynamic and QoL parameters were also not significantly different. The mean age was 56.3 (SD 10.0), mean BMI 26.9 (SD 4.5), mean parity 2.0 (SD 0.8), mean ICIQ 14.9 (SD 2.6) and IQoL 53.8 (SD 10.9), mean MUCP 43.7 cm H2O (SD 16.8) and mean Qmax 27 ml/s.There were no serious perioperative complications in the TVT-O group. In the TVT - S H group there was one bladder perforation and two incidents of blood loss over 500 ml (once required transabdominal surgical revision of bleeding in the Retzius space). The mean blood loss in the TVT -O group was 24.93 ml, in the TVT - S H group 56.80 and in the TVTS-U 42.85 ml (differences were statistically significant). Median follow up after surgery was 1.9 years. The objective cure rate in the TVT-O group was 91.1%, while the other figures were TVT- S U group: 72.3% and TVT- SH group: 70.3%. In the TVT-O group only one result was evaluated as a failure (1.4%), though in the TVT- SH group 11 patients were assessed in this way (17.1%), and 8 of them underwent further anti-incontinence procedures. In the TVT- S U group failure occurred in 9 cases (13.8%), and 7 of them underwent further anti-incontinent procedures. In the TVT-S groups incidence of tape protrusion was also higher: in TVT - SH group there were 5 cases (7.8%) and in the TVT-S U group 4 cases (6.1%), comparing to one in the TVT-O group (1.4%).

Conclusions:

The long-term follow-up revealed a significantly lower subjective and objective cure rate in the TVT SECUR group comparing to the TVT-0 group. There were no significant differences in the cure rates between U and H approach within the TVT - S group.

References (optional):

Presentation Number: 004

SHORT-TERM RESULTS OF PELVIC FLOOR MUSCLE TRAINING OR MIDURETHRAL SLING SURGERY FOR FEMALE STRESS URINARY INCONTINENCE: A RANDOMISED CLINICAL TRIAL

J. LABRIE[1], B. BERGHMANS[2], T. LAGRO-JANSSEN[3], C. H. VAN DER VAART[1], Portret Study Group;
[1]Univ. Med. Ctr. Utrecht, Utrecht, Netherlands, [2]Pelvic Care Ctr. Maastricht, Maastricht Univ. Med. Ctr., Maastricht, Netherlands, [3]Radboud Univ. Nijmegen Med. Ctr., Nijmegen, Netherlands.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: No

Objective:

The objective of this RCT was to compare the effect of pelvic floor muscle training (PFMT) or midurethral synthetic sling surgery for the subjective cure of stress (SUI) and urge incontinence (UUI) symptoms in treatment naïve women with moderate to severe stress urinary incontinence.

Background:

PFMT is advocated in international guidelines to be the first-line treatment for SUI. When PFMT is unsuccessful, a midurethral synthetic sling procedure is the next option. These two treatment options have never been compared directly as primary treatment options in a randomised study. This abstract will focus on the short term outcomes of both interventions for SUI and UUI symptoms.

Methods:

From March 2008 till May 2010 patient inclusion for a multi-center RCT (24 centers) was conducted in the Netherlands. Subjects were women with moderate to severe predominant SUI as measured with the Sandvik index[1]. They were treatment naïve or had not had specialised PFMT for at least 6 months prior to inclusion. Women were randomised for either PMFT by specialised physiotherapists (once weekly, including biofeedback, according to the national guidelines, up to 9–18 sessions) or midurethral synthetic sling procedure (retropubic or transobturator). At baseline and 4 months follow-up subjective symptoms were assed with the patient global impression of severity and improvement index (PGI-S, PGI-I)[2]. This simple, one question outcome measure is commonly used in incontinence research. The PGI-S was dichotomised into severe or mild symptoms (including absent) and the PGI-I into improvement or no improvement (including worse symptoms). The presence or absence of SUI and UUI symptoms was assessed with two questions from the UDI (shown in table 3). Sample size calculation was based on an expected difference in subjective cure of 15% and resulted in 200 women for each arm to detect a difference with a power of 0.9 at an alpha of <5%. We expected a lost to follow-up of 15% and therefore we aimed to include 460 women in the study. Analyses were performed on intention-to treat basis. Data of chi-square statistics are presented in 2×2 tables with odds ratios and 95% confidence intervals.

Results:

Two hundred thirty-one women were randomised for surgery and 231 for PFMT. At 4 months follow up 20 patients in the PFMT group were operated after PFMT. In the surgery group one patient received additional PFMT after surgery. Table 1 and 2 show the PGI-S and PGI-I results at baseline and at 4 months follow up respectively. At 4 months follow-up significantly more women in the PFMT group (39.3%) than women in the surgery group (6.3%) still considered their incontinence

symptoms as severe. Also 41% of women in the PFMT group reported to experience no improvement of their symptoms as compared to 3.1% in the surgery group. At baseline all women experienced SUI and 63.6% of women in the PFMT group and 60.5% of women in the surgery group reported UUI symptoms (OR 1.14, 95% confidence interval 0.77–1.17). Table 3 shows the number of women in both groups who reported SUI and UUI at 4 months follow-up. Subjective cure of both SUI and UUI occurred significantly more often in the surgery group as compared to the PFMT group.

Table 1. Patient Global Impression of Severity

Baseline			**4 months follow-up**	
PFMT (n=195)	Midurethral tape (n=211)	OR (CI)	PFMT (n=183)	Midurethral tape (n=190)
125 (64.1%)	142 (67.3%)	ns	72 (39.3%)	12 (6.3%)

OR corrected for PGIS t= 0; Age; Sandvik index; BMI and Randomisation outcome

Table 2. Patient Global Impression of Improvement

	Baseline			**4 months follow-up**		
PFMT	Midurethral tape	OR (CI)	PFMT n=183	Midurethral tape n=191	OR (CI)	
Not Improved	na	Na	na	75 (41.0%)	6 (3.1%)	18.80 (7.82–41.17)

OR corrected for PGIS t= 0; Age; Sandvik index; BMI and Intervention; na = not applicable

Table 3: Presence of stress and urge incontinence

Positive answer to: Do you experience urine leakage related to physical activity, coughing or sneezing?						
	Baseline			**4 months follow-up**		
	PFMT n=196	Midurethral tape n=212	OR (CI)	PFMT n=183	Midurethral tape n=191	OR (CI)
SUI	196 (100%)	212 (100%)	ns	151 (82.5%)	26 (13.6%)	30.30 (16.95–52.63)
Positive answer to: Do you experience urine leakage related to the feeling of urgency?						
	Baseline			**4 months follow-up**		
	PFMT n=198	Midurethral tape n=210	OR (CI)	PFMT n=183	Midurethral tape n=192	OR (CI)
UUI	126 (63.6%)	127 (60.5%)	1.14 (0.77–1.71)	74 (40.4%)	45 (23.4%)	2.22 (1.42–3.46)

OR corrected for PGIS t= 0; Age; Sandvik index; BMI and Intervention; ns = not significant

Conclusions:
At short term follow-up, women with moderate to severe SUI who underwent surgery were significantly more likely to experience symptom-relief, improvement of symptoms, and subjective cure from SUI but also UUI as compared to women that were allocated to PFMT. This work is presented on behalf of the Dutch Urogynaecology Consortium and we would like to thank the colleagues of the 24 partcipating hospitals for their contribution to the PORTRET study.

References:
1. J Epidemiol Community Health. 1993 Dec;47(6):497–9, 2. *Am J Obst Gynecol*, *189*(1), 98–101

Presentation Number: 005

A MULTICENTRE RANDOMISED TRIAL COMPARING SINGLE-INCISION MINI-SLING (AJUST©) AND TENSION-FREE VAGINAL TAPE-OBTURATOR (TVT-O) IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE

A. MOSTAFA[1], W. AGUR[2], M. ABDEL-ALL[3], M. YOUSEF[4], M. ALLAM[5], K. GUERRERO[6], C. LIM[7], M. ABDEL-FATTAH[1];
[1]Univ. of Aberdeen, Aberdeen, United Kingdom, [2]Ayrshire & Arran NHS, Ayrshire, United Kingdom, [3]NHS Borders, Borders, United Kingdom, [4]Greater Glasgow & Clyde Hlth. Board, Inverclyde, United Kingdom, [5]NHS Lanarkshire, Lanarkshire, United Kingdom, [6]Greater Glasgow & Clyde Hlth.Board, Glasgow, United Kingdom, [7]NHS Fife, Fife, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objectives:
To compare Single-incision Mini-slings (SIMS- Ajust©) versus standard mid-urethral sling (TVT-OTM) in women with stress urinary incontinence (SUI) as regards:

- Postoperative pain profile (primary outcome), hospital stay, peri-operative complications and recovery time.
- Short-term patient-reported & objective cure rates.
- Impact on women's quality of life (QoL) & sexual function

Background:

Mid-urethral slings (MUS) are the most commonly performed procedures for SUI; the vast majority are performed under general anaesthesia (GA)1. SIMS were introduced in 2006 aiming to reduce post-operative pain, recovery time, peri-operative morbidity & consequently improve women's QoL while maintaining equivalent efficacy to standard MUS

Methods:

A multicentre prospective randomised trial in 6 UK centres. Ethical committee approval was obtained and the study was registered on www.clinicaltrials.gov. All eligible women admitted for MUS in the period between October 2009 and October 2010 were invited to participate. Women were included if they had urodynamics SUI or mixed incontinence with pre-dominant bothersome SUI; having failed or declined pelvic floor muscle training. Women were excluded if they had pelvic organ prolapse (≥ stage 2), previous continence surgery and/or concomitant surgery.

Randomisation was done through a number-allocation software and using a telephone randomisation on the procedure day. Women underwent either SIMS- Ajust© (C. R. Bard, Inc., New Jersey, USA) under L.A as an opt-out policy or TVT-OTM (Ethicon Inc., Somerville, USA) under GA. Procedures were done as originally described and cystoscopy was performed for all cases.

Postoperative pain profile was assessed on a 10point visual analogue scale at fixed-time points. All women received a structured telephone interview at 4 days & 4 weeks postoperatively to assess pain score and time to return to work/normal activities. Women completed validated symptom severity questionnaires (International Consultation on Incontinence Questionnaire ICIQ-SF; Urgency Perception Scale (UPS)) and quality of life questionnaires (Kings Health Questionnaire (KHQ), PISQ-12) pre-operatively and at 3 month follow-up. In addition they completed Patient Global Impression of Improvement (PGI-I) and underwent cough stress test and vaginal examination at 3 month.

Power analysis was done & Data was analysed using SPSS 18.0 (Chicago, Illinois). Descriptive analyses are given and between group comparisons were performed using Chi-Square, Fischer Exact test & Mann- Whitney test as appropriate. Significance level was set at 5%.

Results:

137 women were randomised; SIMS (n=69) vs. TVT-OTM (n=68) during the study period; 136 women (99%) completed their 3 month follow-up; women in the SIMS group had significantly lower postoperative pain scores at all time-points assessed and up-to 4 weeks after surgery; shorter hospital stay and earlier return to normal activities/work. There were no significant differences in patient-reported and objective success rates between both operations at 3 month follow-up (Table 1).

124 Women (90.5%) completed a valid KHQ pre & postoperatively; 110 (88.7%) women had ≥10 points improvement in total KHQ score with no significant differences between both groups (SIMS n=54 (85.7%) vs. TVT-OTM n=56 (93.3%), p=0.179 OR2.33, 95%CI 0.678, 8.028). All KHQ domains showed statistically & clinically significant (≥10 points) postoperative improvement with no significant differences between groups (Table 2).

Only 53% (n=72) women have resumed sexual activity at 3 month follow-up; 53/72 women (73.6%) showed an improvement in their PISQ-12 scores (SIMS n=27 (71.1%) vs. TVT-OTM n=26 (76.5%), p=0.603, OR 1.324, 95%CI (0.460, 3.814) (Table 2).

Conclusion:

Adjustable SIMS Ajust© had significantly better postoperative pain profile, earlier return to work and normal activities when compared to TVT-OTM with no evidence of significant differences in women's QoL on short term follow-up. At 3 month only half of the sexually active cohort has resumed their sexual life. Long-term follow-up of this RCT is underway to ascertain if this new procedure lives up for its potential.

References:

1. Stress incontinence surgery in the UK. ICS/IUGA - 2010 Abstract

Table 1. Operative Data & Peri-Operative Complications

	TVT-O™	SIMS-Ajust©	*P*-value
Operating time (min); Mean ± SD	00:33±00:09	00:33±00:10	0.516
Estimated Blood loss: <50 ml	28(41.8%)	45(65.2%)	0.023
50–100 ml	36(53.7%)	22(31.9%)	
>100 ml	3 (4.5%)	2(2.9%)	
Peri-operative Complications:			
Bladder/Urethral Injuries; n (%)	0	0	0
Difficulties in Kit insertion; n (%)	2 (3.0%)	4 (5.8%)	0.681
Severe post-operative pain (score>5/10)	5 (7.5%)	2 (2.9%)	0.271
Voiding dysfunction:			
Requiring Catheterisation	8 (11.8%)	3 (4.3%)	0.200
CISC at 3 month	2 (2.9%)	1 (1.4%)	0.619
Hospital stay (hours); Median(IQR)	05:13 (03:49,09:27)	04:06 (02:58, 05:33)	0.001
Admission over night; n (%)	16 (23.5%)	11 (15.9%)	0.367

Vaginal Erosion	2(2.9%)	0 (0%)	0.496
Postoperative Pain Score (Median (IQR))			
At 30 min	1.00(0.00, 5.00)	0.00(0.00, 0.00)	<0.001
At 3 h	3.00(1.00, 5.00)	0.00(0.00, 1.00)	<0.001
At decision of discharge	3.00(1.00, 4.75)	0.00(0.00, 1.00)	<0.001
At 4 days	2.00(0.00, 4.00)	0.00(0.00, 2.00)	0.001
At 4 weeks	0.00(0.00, 0.00)	0.00(0.00, 0.00)	0.119
Total Pain Profile	2 (0, 4)	0 (0,0)	<0.001
Time To Return To Normal Activities(days)	8 (5.25, 14)	7 (3,14)	0.029
Time To Return To Work (days)	21(11, 28)	14(7, 21)	0.047
Patient Reported & Objective Outcomes:			
Patient-Reported Success (PGI-I) ♣	63 (92.6%)	5 (85.3%)	0.273
Mean Change in ICIQ-SF (Pre-Post); Mean ± SD	12.32±4.50	11.21±5.61	0.205
Patient Satisfaction on Visual Analogue Scale; median (IQR)	9 (8,10)	10 (8,10)	0.243
Recommend To Friend; n (%)	61(91.0%)	63 (92.6%)	0.980
Changes in Urgency on UPS[[Unsupported Character - ♠]]			
Cure of Urgency	20 (29.4%)	19 (27.5%)	0.957
Improvement of Urgency	16 (23.5%)	14 (20.3%)	0.801
No Changes	26 (38.2%)	20 (29.0%)	0.334
Worsening of Urgency	3 (4.4%)	5 (7.2%)	0.718
De-Novo Urgency	3 (4.4%)	10 (14.5%)	0.085

*PGI-I = Patient Global Impression of Improvement; success = = Very/Much Improved *UPS = Urgency Perception Scale*

Presentation Number: 006

DOES BMI AFFECT THE RESULTS OF CONTINENCE SURGERY? AN ANALYSIS OF THE BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG) DATABASE

N. ASLAM[1], P. A. MORAN[2], R. ASSASSA[3];
[1]Worcestershire Royal Hosp., Worcester, United Kingdom, [2]Worcestershire Royal Hosp., Worcester, United Kingdom, [3]Mid Yorkshire NHS Trust, Mid Yorkshire, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to identify the impact of body mass index (BMI) on the efficacy of RMUS (Retropubic midurethral sling) for stress urinary incontinence and to see if there were differences in intra-operative and post operative outcome in women with differing BMI.

Background:
Little data is available on the outcome of retropubic mid urethral slings (RMUS) procedures in obese and overweight women. It is often thought that high BMI may be a contributing factor to intra operative complications and poor surgical outcome for continence surgery.

Methods:
The BSUG surgical database asks surgeons to prospectively enter their patients demographics (including BMI) when performing surgery. The data base looks at all forms of both prolapse and continence surgery and has collected over 22,000 surgical episodes to date since 2007.Cases were selected from the BSUG database if they had undergone retropubic MUS, did not have any other concomitant surgery, and were having primary continence procedures. We compared pre- and postoperative evaluations, including subjective and objective outcome, complications, and quality of life assessed by validated
Questionnaires.

Results:
Up until the end of 2010 there were 3925 cases who also had BMI data entered. BMI had no effect on anaesthetic choice; GA was most commonly used among all groups.
Complications were recorded as per the BSUG database. Bladder perforation rates appear higher among the patients with low/normal BMI (4.4%VS 2%), however blood loss was similar in all groups. There seem to be no trend between BMI and return to theatre within 72 h, catheterisation beyond 72 h or return to hospital within 30 days. Outcome data was sporadic. 1529 (38%) of the cases had no follow-up data entered but this was consistent for all categories of BMI. Median follow up was 17 weeks (range 6–52 weeks)
Cure/improvement rates for stress incontinence were similar throughout the BMI ranges. Morbidly obese women seemed overall less satisfied with the outcome of their surgery with respect to PGI (69% vs. 86–91%). Interestingly, cure/improvement rates for urgency/urgency incontinence appeared lower (57% vs. 72–88%) in the morbidly obese group. In addition, a significant proportion of morbidly obese women had a worsening of their urgency symptoms post-operatively (20%vs 3–5%). The rate of

new de novo urgency symptoms post-operatively did not differ between the groups (3–4%).

Conclusions:

Morbid obesity (BMI >40) does not seem to be associated with a poorer outcome for incontinence surgery in UK with respect to SUI symptoms. However, morbidly obese patients seem less satisfied overall with respect to global impression of outcome for incontinence. This may possibly related to the lower impact that surgery appears to have on pre-existing urgency symptoms or indeed a deterioration in such symptoms in this particular group. This may be useful information when counselling our morbidly obese patients prior to undergoing a RMUS procedure for mixed incontinence symptoms.

Table1- Demographics details, Anaesthesia used and complications:

BMI	<20	20–25	25–30	30–35	35–40	>40
Number (n)	67	1051	1487	863	375	147
Mean age	49	52	54	53	52	54
USI only (%) [i.e. not mixed]	78	77	73	72	69	67
Anaesthetic n (%)						
GA	41 (61%)	668 (64%)	979(66%)	567(66%)	238(63%)	90(61%)
Spinal	7 (10.4%)	134(12.7%)	206(14%)	133(15.4)	66(18.4%)	32(22%)
LA with sedation	18 (27%)	230(22%)	282(19%)	151(17.4)	65(17.3%)	21(14%)
Local alone	1 (1.5%)	9(0.85%)	7(0.47%)	5(0.5%)	3(0.8%)	1(0.68%)
Bladder injury	3(4.4%)	47(4.4%)	44 (2.95%)	17(1.96%)	3(0.8%)	3(2.04%)
>500 ml blood loss	0	9(0.85%)	6 (0.40%)	5(0.57%)	4(1.06%)	0

Table 2- Outcome reported

BMI	<20	20–25	25–30	30–35	35–40	>40
Change in stress incontinence						
Cured	25(76%)	426(75%)	634(78%)	332(74%)	134(71%)	41(63%)
Improved	5(15%)	121(21%)	158(19%)	94(21%)	45(24%)	16(25%)
No Change	3(9%)	16(3%)	21(2.5%)	19(4.2%)	8(4.2%)	8(0.5%)
Worse		3(0.5%)	4(0.4%)	5(1%)	1(0.5%)	
Change in Urgency/urge incontinence						
Cured/not present	23(70%)	306(56%)	448(56%)	221(51%)	86(48%)	24(35%)
Improved	3(9%)	123(22%)	162(20%)	96(22%)	44(24%)	15(22%)
No Change	5(15%)	75(14%)	108(14%)	72(17%)	35(19%)	14(20%)
Worse	1(3%)	21(4%)	44(6%)	30(7%)	9(5%)	14(20%)
New Symptom	1(3%)	25(4%)	31(4%)	15(3%)	7(4%)	2(3%)

Table 3- Outcome reported

BMI	<20	20–25	25–30	30–35	35–40	>40
Global Impression of Improvement in incontinence (PGI-I)	28(90.3%)	526(92%)	744(91%)	389(87%)	166(86.4%)	48(69%)
Very much/much better	2(6.4%)	22(4%)	41(5%)	25(6%)	14(7%)	11(16.4%)
A little better	0	14(0.2%)	18(2%)	21(5%)	6(3%)	5(7.4%)
No change	0	6(1%)	5(0.6%)	7(1.6%)	2(1%)	1(1.5%)
A little worse	0	2(0.3)	7(0.8%)	2(0.4%)	4(2%)	2(3%)
Much worse	1(3.2%)	4(0.6)	2(0.2)	4(0.9%)	0	0
Very much worse						
ICIQ-UI score Pre-op (mean)	11.6	12.01	11.73	12.43	12.53	12.31
ICIQ-UI score Post-op (mean)	2.04	2.36	2.72	2.96	3.37	4.11

Presentation Number: 007

SYSTEMATIC REVIEW OF POLYDIMETHYLSILOXANE INJECTION: SHORT AND LONG TERM DURABILITY OUTCOMES FOR FEMALE STRESS URINARY INCONTINENCE

G. M. GHONIEM;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: Yes

Objective:
To review the scientific literature for efficacy of the urethral bulking agent (UBA) Macroplastique in the treatment of adult females diagnosed with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD).

Background:
SUI is a debilitating and dynamic condition affecting millions of women worldwide. There are several treatment options for SUI ranging from behavior modification to surgical repair. Urethral bulking agents have been widely used with minimal invasiveness, however long term durability varies between products, as resorption, allergic reactions, and migration can occur in some UBAs. Macroplastique has been used worldwide since 1991 with long-term documented safety and efficacy.

Methods:
Ovid MEDLINE, PubMed and the Cochrane Library were used to conduct systematic reviews of SUI for peer-reviewed articles on clinical outcomes for Macroplastique. Articles included in the meta analysis included only those studies from randomized control trials, prospective, observational and cohort studies. Publications with the same cohort sample were excluded. Eight-two publications were retrieved from the searches with 19 patient cohorts from 20 published articles used in this systematic review. Individual study outcomes were extracted and transformed to create a meta-analytic database. General linear (random-effects) models to obtain estimates for short term (6–24 week), 1 year (12–18 months) and long term (>18 months) efficacy of Macroplastique on adult female SUI while controlling for known covariates of year of treatment, volume injected and reinjection rate.

Results:
19 patient cohorts in 20 published studies of 817 patients were examined. Short term data showed Macroplastique was successful in improving SUI in 73% (65–81%) of adult female patients with a 45% (33–57%) cure rate. At 1 year, improvement and cure rates were stable at 73% (59–84%) and 41% (29–54%), respectively. In the long term (18+months), 64% (57–71%) of patients maintained their improvement with 38% (28–48%) considered cured. Cure rates at 2 years were not statistically different from those reported in the short term. 30% (20–42%) of patients received a second treatment. See table.

Conclusions:
Results from this systematic review and meta-analysis support the short and long-term efficacy and durability of Macroplastique.

		No. Publications	No. Subjects	Pooled Proportion [95% CI]
Short Term (6–24 weeks)	**Cure**	11	422	**45%** [33–57%]
	Improved	9	352	**73%** [65–81%]
Mid Term (12–18 months)	**Cure**	9	421	**41%** [29–54%]
	Improved	8	389	**73%** [59–84%]
Long Term (>18 months)	**Cure**	10	404	**38%** [28–48%]
	Improved	9	370	**64%** [57–71%]

Presentation Number: 008

DOES MODE OF DELIVERY AFFECT PELVIC ORGAN SUPPORT AND QUALITY OF LIFE? A LONGITUDINAL 5 YEAR STUDY

K. ELENSKAIA, R. THAKAR, A. H. SULTAN, I. SCHEER, R. SRIVASTAVA, J. L. ONWUDE;
Croydon Univ. Hosp., London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To prospectively evaluate the impact of childbirth on pelvic organ support and the effect of symptoms on quality of life (QoL) in the short, medium and long-term using validated measures.

Background:
Epidemiological studies estimate childbirth to be the strongest risk factor for pelvic organ prolapse (POP) (1). However, only two prospective studies (2, 3) with short term follow-up have analysed the role of childbirth on POP using the validated POPQ staging method. Although these were objective studies, they did not longitudinally evaluate prolapse related symptoms and its effect on QoL.

Methods:
Between April 2005 and July 2006 women over 18 years of age with a singleton pregnancy were recruited to complete the paper version 3 of the electronic Personal Assessment Questionnaire (ePAQ -PF) at median 20 weeks (Visit 1). POP was

assessed in the left lateral position using the validated POPQ. The questionnaire and POPQ were repeated after delivery, at 14 weeks (Visit 2), 1 year (Visit 3) and 5 years (Visit 4). Demographic and obstetric details were recorded. Ethical approval (REC No: 05/Q0806/9) and informed consent was obtained.

Results:

182 nulliparous women (mean age 30, range 17–45) completed the questionnaire and POPQ was performed in 175 women (96%) at Visit 1. 129 (71%) attended (Visit 2), 78 (43%) (Visit 3) and 97 (53%) (Visit 4). The following numbers of questionnaires and POPQ were completed: Visit 2=126/126 (69.2%), Visit 3=90 (49.5%)/77(42.3%), Visit 4=94 (51.7%)/97 (53.3%). Table 1 demonstrates the longitudinal changes in POPQ. Mode of delivery was not known in 5 patients. Table 2 shows longitudinal changes in POPQ stage after vaginal delivery (VD) and caesarean section (CS) for 170 patients. Compared to the baseline Visit 1, vaginal prolapse symptom scores worsened significantly after VD at all postnatal visits ($p<0.01$) and bother at Visits 2 and 4 ($p<0.03$). No significant changes in symptoms occurred after CS. No significant changes occurred in QoL following VD or CS. On sub analysis excluding those who delivered subsequently between 1 and 5 years [still primiparous VD ($n=32$) and CS group ($n=14$)] we found the following: After VD, symptom scores, bother and QoL had no significant change; POPQ changed significantly at Visit 4 ($p=0.01$) compared to Visit 1. After CS no changes were found in any parameters. There was no difference between Visit 3 and 4.

Conclusion:

Apart from a significant temporary worsening in POPQ stage soon after CS, it recovers and CS is not associated with any changes in the long term. By contrast, VD is associated with worsening symptoms and POPQ stage shortly after VD and this is sustained in the long term but there is no change in vaginal QoL. Our findings suggest that the early changes in pelvic organ support in primiparous women do not deteriorate in the longer term and as there are no bothersome symptoms or changes in QoL, it is possible that these changes are physiological and we plan to follow up these women to determine which women develop clinical prolapse.

References:

1 Am J Obstet Gynecol 2006;194:75–81
2 Obstet Gynecol 2002;100:981–86
3 Int Urogynecol J Pelvic Floor Dysfunct. 2005;16:69–72

Table 1: Longitudinal comparison of POP-Q stage in primiparous women irrespective of their mode of delivery

	Baseline 20 weeks		**14 weeks postnatal**		**1 year**		**5 years**	
Frequency of POPQ stages	*N*=175		*N*=126		*N*=77		*N*=97	
0	N%		N%		N%		N%	
1	84	48	11	9	25	32	26	27
2	76	43	82	65	40	52	40	41
3	15	9	33	26	12	16	28	29
	0	0	0	3	3			
Average POPQ Stage			1.2		0.83		1.08	
Change in average score from baseline[p-value]	0.61		0.61 [0.000]		0.27 [0.003]		0.44 [0.000]	

Table 2: Longitudinal comparison of POPQ in women who were nulliparous at Visit 1

	Vaginal delivery (n=125)	**Caesarean delivery (n=45)**
	Change in average stage from 2nd trimester	Change in average stage from 2nd trimester
	N	N
	p-value	p-value
14 weeks	0.67	0.41
	93	29
	0.000	0.01
1 year	0.40	−0.19
	57	16
	0.000	0.30
5 years	0.43	−0.14
	30	14
	0.01	0.63

Presentation Number: 009

SECOND STAGE OF LABOR WITH POSTURAL CHANGE AND LATERAL POSITION IN WOMEN WITH EPIDURAL ANALGESIA: A RANDOMIZED CONTROLLED TRIAL

C. WALKER[1], T. RODRÍGUEZ[1], A. HERRANZ[2], I. M. GARCÍA[2], J. A. ESPINOSA[3], E. SÁNCHEZ[4], M. ESPUÑA[5]; [1]Univ. Europea de Madrid, Madrid, Spain, [2]Hosp. Univ.rio La Paz de Madrid, Madrid, Spain, [3]Hosp. Univ.rio Quirón, Madrid, Spain, [4]Univ.t Ramon Llull, Barcelona, Spain, [5]Univ. de Barcelona, Madrid, Spain.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate the effects of an alternative model of birth based on the combination of postural changes, during the passive phase of the second stage of labor and lateral position during the active pushing phase, in labor with epidural analgesia, on the incidence of assisted vaginal delivery and perineal trauma.

Background:
Maternal mobility during the second stage of labor in women with epidural analgesia has had little attention although there are a number of strategies based on postural biomechanical analysis that can be used to facilitate the progress of labor. Delaying the onset of pushing has been proposed as an alternative that reduce the instrumental delivery rate. However, none of the trials of delayed pushing detail the positions of the women during the resulting passive expulsive phase. A recent trial shows that mobility during the first stage of labor has not demonstrated a specific beneficial impact on mode of delivery, however the effect of mobility after full cervical dilatation in second stage remains equivocal(1). On the other hand, lateral position has been associated with the most favorable perineal outcome profile (2). Lateral position is easy to use for delivery in women with epidural analgesia and allows the spine and the pelvis rest in a neutral position and with internal rotation of the hip. These biomechanical factors could have a positive influence in the progress of labor.

Methods:
This is a prospective randomised controlled trial. One hundred ninety-nine women with epidural anesthesia were randomised at full cervical dilatation to a traditional model of birth (TMB) (n=96) or an alternative model of birth (AMB) (n=103). Women in TMB commenced pushing immediately after randomization and delivered in lithotomy position. In AMB women followed a postural changes protocol while they delayed pushing and used specific lateral position for delivery. Statistical analyses were performed using Pearson chi-square for categorical and Student t test for continuous variables. Logistic regression models were used to evaluate whether obstetrical factors/interventions were independently associated with assisted vaginal delivery, as well as with perineal trauma. p values lower than 0.05 were considered statistically significant.

Results:
AMB was associated with a significant reduction in assisted vaginal delivery compared with TMB (19.8% vs 42.1%, $p<0.001$). Maternal results are shown in Table 1. TMB was strongly associated with assisted vaginal delivery (OR=4.49; $p<0.05$) which, in turn, was significantly associated with nulliparity (OR=5.52; $p<0.005$) and fetal head unengaged at full dilatation (OR=5.35; $p<0.05$). Variables independently associated to assisted vaginal delivery in the regression model fitted are shown in Table 2. Among spontaneous vaginal deliveries, AMB significantly increased the intact perineum rate compared with TMB (40.3% vs 12.2%, $p<0.001$). Episiotomy rate was significantly reduced in AMB (21.0% vs 51.4%, $p<0.001$) and there were no differences in perineal tears among spontaneous vaginal deliveries. All assisted vaginal delivery turned in perineal trauma, and prolonged pushing (OR=1.04; $p<0.05$), but not prolonged second stage of labor was associated with perineal trauma.

Table 1. Maternal data.
Data are presented as means (standard deviation) or numbers (%)
AMB (Alternative Model of Birth)
TMB (Traditional Model of Birth)
SVD (Spontaneous Vaginal Delivery)
* $p<0.001$
$^{\alpha}$(19 women of the AMB changed from lateral to lithotomy position during the active phase of the second stage of labour, due to medical or maternal reasons)

Maternal results	***TMB (n=101)***	***AMB (n=95)***
Delivery mode:		
SVD - Lateral position	–	62(61.4)
VD - Litothomy position	55(57.9)	19 (18.8)$^{\alpha}$
Assisted vagin l delivery	40(42.1)	20(19.8)*
Duration of 2nd stage of labor	52.06(36.2)	85.52(52.1)*
Duration of pushing phase	47.69(32.4)	31.32(25.8)*
Perineal outcomes:		
Episiotomy (SVD only)	27(49,1)	13(21)*
Intact perineum (SVD only)	7(12.7)	25(40.3)*
1st degree perineal tear	21(38.2)	26(41.9)
2nd degree perineal tear	3(5.5)	2(3.2)
3rd degree perineal tear	1(1.8)	–

Table 2. Logistic regression model

Variable	Adjusted Odds Ratios	p-value	95% confidence interval
Nulliparity	5.52	<0.004	1.74–17.51
Fetal head unengaged at full dilatation	5.35	<0.021	1.29–22.26
TMB	4.49	<0.036	1.10–18.37

TMB (Traditional Model of Birth)

Conclusion:
Combination of postural changes during the passive expulsive phase of labor and specific lateral position during active pushing time is associated with a reduction in assisted vaginal delivery and perineal trauma.

References:
1. Anaesthesia 2009;64:266–72.
2. Birth 2002;29:18–27

Presentation Number: 010

DOES LEVATOR TRAUMA 'HEAL'?

K. SHEK, H. DIETZ;
Univ. of Sydney, Penrith, Australia.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To compare levator ani morphology, hiatal area and pelvic organ support at 4 months and 2 years after a first vaginal delivery.

Background:
Levator trauma may be the missing link between childbirth and female pelvic organ prolapse (FPOP). Apart from levator avulsion ('macrotrauma'), traumatic overdistension of the levator ('micro-trauma') may also play a role (1). Both are commonly identified 3–6 months after childbirth. It is not clear as to whether such changes evolve over time, or whether they remain static.

Methods:
488 nulliparous women previously recruited between 36 weeks and 38 weeks were invited for an assessment at 3–6 months and again at 2–3 years after childbirth. All underwent an interview and 4D translabial ultrasound performed after voiding, at rest, on maximum Valsalva and on maximum pelvic floor contraction (PFMC) with a GE Kretz Voluson 730 expert system. Volume datasets were analysed with proprietary software. Hiatal areas and bladder neck descent (BND) were determined as previously described (1,3).

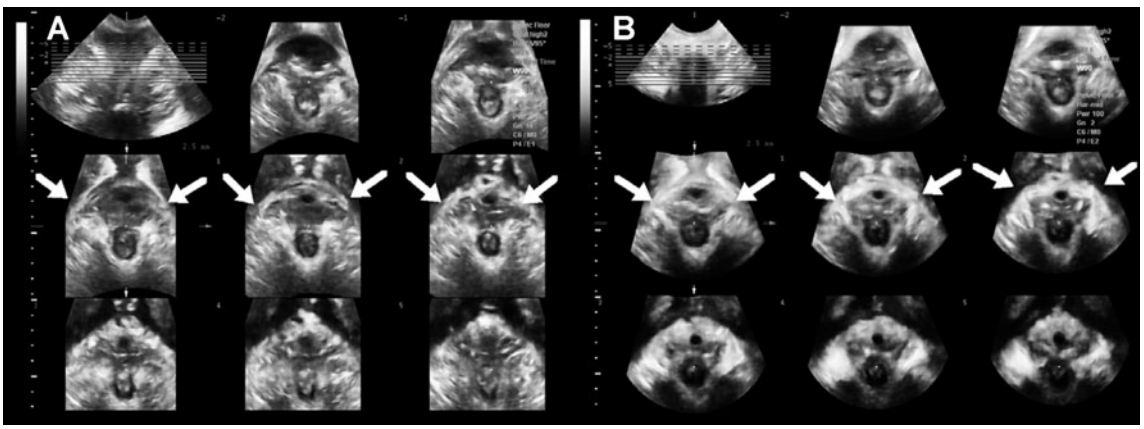


Fig. 1: TUI representation of bilateral avulsion (arrows) at 3 months postpartum (A), same patient 2 years 5 months later (B) showing partial trauma only (arrows).

Results:
367 and 161 participants returned for assessment at 4.1 months (IQR 3.7–5) and 2.6 years (IQR 2.0–3.1) respectively. Demographics of the 367 women have been reported previously(2). Mean age of the 161 women was 29.8 years (±5.4), mean BMI 27.1(±6.0), 97% were Caucasian. At the first follow-up 5 were pregnant again, at the 2nd follow-up 6 were pregnant and 7 were <3 months postpartum after a 2nd delivery. They were excluded, leaving 362 and 148 for analysis (Table 1).

Table 1: Mean hiatal area and BND at 4.1 months and 2.6 years postpartum. Values are mean (SD) in cm2 for hiatal areas and mm for BND.

	Area at rest	Area on Valsalva	Area on PFMC	BND
Follow-up at median 4.1 months (n=362)	14.6 (±3.1)	22.0 (±7.2)	12.4 (±2.7)	26.3(±11.4)
Follow-up at median 2.6 years (n=148)	15.6 (±2.9)	22.0 (±7.3)	12.8 (±2.7)	25.5(±10.7)
P	<0.001	0.95	0.23	0.49

Out of 148, 138 have both postpartum datasets for evaluation, allowing pairwise comparison. 89 had a vaginal delivery in their first pregnancy. By the time of their second appointment, 61 women had at least one more delivery (37 vaginal); 77 had no further births. Analysis of this subgroup revealed similar findings (Table 2). A subgroup analysis comprising only women who had originally delivered vaginally (n=53) yielded almost identical results except a significant reduction in BND (31.2 vs 28.3 mm, P=0.025).

At the 3–6 month follow-up, 12 women were diagnosed with avulsion. At 2–3 years 3 were considered negative for avulsion. Their volumes were reviewed. In one case the first diagnosis was likely a false positive due to partial trauma. The other two cases showed clear signs of improvement in appearances on tomographic ultrasound.

Table 2 Mean hiatal areas and BND at 4.1 months and 2.6 years postpartum of women without further deliveries (n= 77).

	Area at rest (n=76)	Area on Valsalva (n=73)	Area on PFMC (n=73)	BND (n=76)
Follow-up at median 4.1 months	14.6 (±3.1)	22.9 (±7.3)	12.3 (±3.0)	28.1 (10.5)
Follow-up at Median 2.6 years	15.5 (±2.8)	22.1 (±7.1)	12.5 (±2.5)	26.5 (10.9)
P	0.03	0.27	0.62	0.12

Conclusion:
We have documented two cases of substantial improvement in imaging appearances of levator trauma over an interval of 2–3 years. However, there is no evidence of regression or healing of delivery- related changes to levator distensibility on comparing imaging data obtained at 3–6 months and 2–3 years. There is no evidence of ongoing deterioration either, despite many women giving birth to a second child in the interval. The latter may argue against the 'ship in dock' hypothesis for the pathogenesis of FPOP.

References:
1. BJOG 2010;117: 1485–92.
2. Am J Obstet Gynecol. 2010;202:586.e1–e6.
3. Ultrasound Obstet Gynecol. 2004;23:80–92.

Presentation Number: 011

EFFECTS OF POSTURAL CHANGES DURING THE SECOND STAGE OF LABOR AMONG WOMEN WITH EPIDURAL ANALGESIA

M. SIMARRO[1], C. WALKER[2], C. SALINAS[1], A. MARTÍNEZ[1], A. HENRÍQUEZ[1], G. GARCÍA[1], J. ESPINOSA[1];
[1]Hosp. Quirón Madrid, Pozuelo de Alarcón, Spain, [2]Univ. Europea de Madrid, Villaviciosa de Odón, Spain.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: No

Objective:
To evaluate the effectiveness of a protocol of postural changes during the second stage of labor among women with epidural analgesia on mode of delivery, perineal trauma and the incidence of urinary incontinence postpartum.

Background:
The introduction of epidural analgesia has led to significant progress in reducing the pain of labor. However, a disadvantage is that it interferes with the normal mechanism of labor and extends the expulsive phase. The inhibition of the pushing efforts and the reduced possibility of adopting alternative position during the second stage of labor could be related with the increased of instrumental delivery in women with epidural analgesia.

Recent studies have shown that maternal movement and position changes during labor with epidural analgesia could reduce instrumental deliveries (1), decrease pain, produce good maternal-fetal circulation, decrease length of labor and decrease perineal trauma (2).

Methods:
We randomly assigned 150 women at full dilation to either and experimental group (EG) (n=73) or control group (n=77). Both groups delayed pushing and used lithotomy position during delivery. Women in the EG were encourage to follow a protocol of postural change between different positions (hands and knees, sitting, lateral, kneeling and supine) which was monitorized by a physiotherapist to assure the neutral position of the lumbo-pelvic spine in all positions. Women in the CG rest in horizontal position without perform postural changes.

Statistical analyses were performed using Pearson chi-square for categorical and Student *t* test for continuous variables. Logistic regression models were used to evaluate whether obstetrical factors/interventions were independently associated with assisted vaginal delivery, as well as with perineal trauma. P values 0.05 lower than were considered statistically significant.

Results:

Instrumental delivery rate was significantly reduced in EG (39% vs 24% in CG and EG, p=0,005) as well as cesarean sections (10.4% vs 1.4%, CG and EG, p=0.05), Table 1. EG was associated with a significant redution in the incidence of episiotomy (31.2% vs 17.8%, CG and EG, p<0.05) while the first-degree perineal tears was increased (32.9% vs 55.7%, CG and EG, p=0.005). The incidence of sphincter tears was significantly higher in CG (five cases in CG vs none in EG, p<0.05). In relation to the incidence of postpartum urinary incontinence, we found no significant differences.

The length of the second stage of labor is shown in Table 2. We found significant reduction on the duration of the second stage of labor in EG (124.30±44.83 and 94.66±32.78 in CG and EG, p<0.001). Another significant finding is that the fetal head station in the EG at the start of the active expulsive phase was at lower level of the birth canal that the fetal head of the CG.

Table 1: Maternal outcomes of childbirth

	Control Group (n=77)	Experimental Group *(n=73)*	P
Spontaneous vaginal delivery	39 (50.6%)	54 (74.0%)	*P*=0.005
Instrumental delivery	30 (39%)	18 (24%)	*P*<0.05
Cesarean Section	8 (10.4%)	1 (1.4%)	*p*<0.05
Episiotomy	24 (31.2%)	13 (17.8%)	*p*<0.05
Intact Perineum	16 (20.8%)	10 (13.7%)	NS
1º Degree perineal tear	23 (32.9%)	39 (55.7%)	*P*=0.005
2º Degree perineal tear	14 (20%)	12 (17.1%)	NS
3º Degree perineal tear	5 (6.5%)	0	*p*<0.05
UI postpartum	28 (36.4%)	25 (34.2%)	NS

(NS) was not significant.
(UI) Urinary incontinence

Table 2: The duration of the second stage of labor

	Control Group (n=69)	Experimental Group (n=72)	P
Lenght of the total expulsive phase (min)	124.30±44.83	94.66±32.78	*p*<0.001
Lenght of the passive expulsive phase (min)	73.87±33.59	50.77±20.54	*p*<0.001
Lenght of the active expulsive phase (min)	50.43±24.56	43.89±23.78	NS
Station presentation at the beginning of passive phase.	**0.71±0.56**	**0.70±0.70**	**NS**

(NS) No significative.

Conclusions:

Promote postural changes during the expulsive phase of labor in women with epidural analgesia is associated with a lower incidence of instrumental delivery, cesarean section and length of second stage of labor. In addition, the protocol present in this trial is associated with a lower rate of episiotomy and sphinter lacerations.

References:

1. Midwifery. 2004. 20: 157–168.
2. MCN Am J Matern Child Nurs. 2010. 35(2): 72–78.

Presentation Number: 012

LIFETIME RISK OF WOMEN UNDERGOING PRIMARY AND REPEAT SURGICAL TREATMENT FOR PELVIC ORGAN PROLAPSE (POP) AND/OR STRESS URINARY INCONTINENCE (UI)

M. ABDEL-FATTAH, A. FAMILUSI, S. FIELDING, S. BHATTACHARYA;
Univ. of Aberdeen, Aberdeen, United Kingdom.

Consent obtained from patients: No
Level of support: Not Applicable
Work supported by industry: No

Objective:

To calculate the lifetime risk of women undergoing primary or repeat surgical treatment for pelvic organ prolapse (POP), stress urinary incontinence (SUI) and/or rectal prolapse/faecal Incontinence (RP-FI). We aim to identify independent risk factors for undergoing primary and repeat surgery.

Methods:

Records of women who were born before 1st January 1968 and who have at least their fist delivery recorded in the Aberdeen Maternity and Neonatal databank (AMND) were linked by the Information and Services Division of the NHS Scotland to SMR01 (hospital episode data) and GRO-S death records using probability matching to generate an anonymous study database extracted on 31st July 2010. Lifetime risk of surgery (from birth to date of operation or censored at death or 31st July 2010 as appropriate) was calculated using Cox regression. Univariate and Multivariate regression models were performed to identify potential independent risk factors for primary surgery using Cox regression & repeated surgery using logistic regression.

Results:

A total of 47103 women were identified in the AMND and 34631 (73%) of them were linked with ISD database; 2922/34631 (8.4%) had a diagnosis of POP/SUI/RP-F1 while 2130 women (6.2%) underwent one or more surgical operation.

Figure 1 shows the cumulative hazard function for all types of POP/SUI/RP-FI surgery; the lifetime risk by age 80 is 12.2%. The lifetime risk of having a SUI operation was 3.6%; a POP operation was 9.5% and of having RAP or FI operation was 0.7%. Table 1 shows the analysis for risk factors of undergoing a primary surgery for a pelvic floor disorder.

Of the 2130 women who had a POP/SUI operation; 407 (19%) women had repeat surgery; 67/762 women (8.8%) underwent repeat surgery for SUI. The risk factors for SUI re-operation are shown in Table 2. Using abdominal retropubic procedures such as colposuspension as the reference group, tension-free vaginal tapes were significantly less likely to have repeat surgery, compared to peri-urethral injectables which were significantly more likely. Figure 2 shows operative trends in SUI over last 30 years.

The risk of repeat surgery for POP was 15.8% (238/1508); risk of repeat surgery in anterior compartment was 8.8% while for posterior compartment it was 7.4%. Table 3 shows the Odd Ratios for potential risk factors for repeat POP operation.

Conclusion:

This epidemiological study established the life-time risk of parous women in a UK population undergoing primary and secondary surgical treatment for female stress urinary incontinence, faecal incontinence and pelvic organ prolapse.

Table 1: Cox Regression Results For Risk Of A Primary Pelvic Floor Surgery

	Operation (N=2130)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery							
SVD/Breech only	1434(67.3%)	1.00					
CS only	27 (1.3%)	*0.25*	*(0.16, 0.36)*	*<0.001*	*0.27*	*(0.18, 0.39)*	*<0.001*
Instrumental (at least one forceps)	589 (27.7%)	*1.14*	*(1.03, 1.26)*	*0.07*	*1.13*	*(1.02, 1.25)*	*0.015*
Instrumental (at least one, but no forceps)	24 (1.1%)	1.42	(0.95, 2.13)	0.09	1.35	(0.90, 2.02)	0.15
SVD + CS	56 (2.6%)	0.92	(0.70, 1.20)	0.53	0.89	(0.68, 1.17)	0.40
Age at 1st delivery							
Under 20 years	357 (16.8%)	*0.88*	*(0.78, 0.99)*	*0.035*	*0.87*	*(0.78, 0.98)*	*0.021*
20–29 years	1530 (71.8%)	1.00			1.00		
30–49 years	243 (11.4%)	1.11	(0.97, 1.28)	0.12	*1.34*	*(1.16, 1.54)*	*<0.001*
Total number of deliveries							
Single	393 (18.5%)	1.00			1.00		
2 to 4	1663 (78.1%)	*1.41*	*(1.26, 1.58)*	*<0.001*	*1.30*	*(1.16, 1.46)*	*<0.001*
5+	74 (3.5%)	1.15	(0.90, 1.48)	0.27	1.10	(0.85, 1.41)	0.48
Twins at some point							
No	2104 (98.8%)	1.00					
Yes	26 (1.2%)	0.80	(0.54, 1.17)	0.25			
Time between deliveries							
One delivery	393 (18.5%)	1.00					
All <2 years	268 (12.6%)	*1.40*	*(1.19, 1.63)*	*<0.001*			
All greater than or equal to 2 years	1047 (49.2%)	*1.40*	*(1.24, 1.57)*	*<0.001*			
Mixture (<2 and >2)	422 (19.8%)	*1.41*	*(1.23, 1.62)*	*<0.001*			
Type of perineal wound							
No wound	764 (35.9%)	1.00			1.00		
All Episiotomy	605 (28.4%)	*1.19*	*(1.07, 1.33)*	*0.001*	1.05	(0.94, 1.18)	0.37
At least one 3 rd degree tear	12 (0.6%)	*1.99*	*(1.12, 3.53)*	*0.018*	1.68	(0.95, 2.97)	0.076
At least one laceration (no tear)	749 (35.2%)	*1.57*	*(1.41, 1.73)*	*<0.001*	*1.36*	*(1.22, 1.52)*	*<0.001*

Table 2: Results Of Logistic Regression For Risk Of Re-Operation For Stress Urinary Incontinence

	SUI operation		Unadjusted Analysis			Adjusted Analysis		
Risk Factor	**One (N=695)**	**> 1 (N=67)**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Type of first SUI surgery								
Abdominal Retropubic Procedures	285 (41.0%)	34 (50.7%)	1.00			1.00		
Tension - Free Vaginal tape	331 (47.6%)	11 (16.4%)	*0.28*	*(0.14, 0.56)*	*<0.001*	*0.30*	*(0.15, 0.60)*	*0.001**
Colporrhapy	66 99.5%)	14 (20.9%)	1.78	(0.90, 3.50)	0.096	1.92	(0.97, 3.82)	0.063
Injectables for UI	5 (0.7%)	5 (7.5%)	*8.38*	*(2.31, 30.4)*	*0.001*	*9.05*	*(2.42, 33.8)*	*0.001**
Urogenital Fistulae (VVF)	8 (1.2%)	3 (4.5%)	3.14	(0.80, 12.4)	0.102	2.50	(0.58, 10.8)	0.22
Mode of delivery								
SVD only	488 (700.2%)	45 (67.2%)	1.00					
CS only	16 (2.3%)	2 (3.0%)	1.36	(0.30, 6.08)	0.69			
At least one forceps	158 (22.7%)	14 (20.9%)	0.96	(0.51, 1.80)	0.90			
At least one instrumental: no forceps	9 (1.3%)	3 (4.5%)	3.62	(0.95, 13.8)	0.06			
SVD + CS	24 (3.5%)	3 (4.5%)	1.36	(0.39,4.68)	0.63			
Age at 1st delivery								
Under 20 years	166 (23.9%)	16 (23.9%)	0.93	(0.51, 1.67)	0.80			
20–29 years	470 (67.6%)	49 (73.1%)	1.00					
30–49 years	59 (8.5%)	2 (3.0%)	0.33	(0.08, 1.37)	0.13			
Total number of deliveries								
One	116 (16.7%)	10 (14.9%)	1.00					
2 to 4	558 (80.3%)	56 (83.6%)	1.16	(0.58, 2.35)	0.67			
5+	21 (3.0%)	1 (1.5%)	0.55	(0.07, 4.55)	0.58			
Occurrence of twins								
No	687 (98.8%)	67 (100%)						
yes	8 (1.2%)	0 (0%)						
Time between deliveries								
One delivery	116 (16.7%0	10 (14.9%)	1.00					
All <2 years	89 (12.8%)	8 (11.9%)	1.04	(0.40, 2.75)	0.93			
All greater than 2 years	354 (19.6%)	10 (14.9%)	1.28	(0.62, 2.64)	0.51			
Mix of <2 and>2 years	136 (19.6%)	10 (14.9%)	0.85	(0.34, 2.12)	0.73			
Type of perineal wound								
No Wound	239 (34.4%)	26 (38.8%)	1.00			1.00		
All Episiotomy	211 (30.4%)	28 (41.8%)	1.22	(0.69, 2.15)	0.49	1.22	(0.68, 2.19)	0.51
At least one 3rd degree tear	1 (0.1%)	1 (1.5%)	9.19	(0.56, 151)	0.12	4.83	(0.25, 92.8)	0.30
At least one laceration (no tear)	244 (35.1%)	12 (17.9%)	*0.45*	*(0.22, 0.92)*	*0.028*	*0.46*	*(0.22, 0.95)*	*0.037**

Table 3: Results Of Logistic Regression For Risk Of Re-Operation For Pelvic Organ Prolapse

	POP operation		Unadjusted		
Risk Factor	**One (N=1270)**	**> 1 (N=238)**	**OR**	**95% CI**	**p-value**
Mode of delivery					
SVD only	857 (67.5%)	164 (68.9%)	1.00		
CS only	7 (0.6%)	0 (0%)			
At least one forceps	365 (28.7%)	65 (27.3%)	0.93	(0.68, 1.27)	0.65
At least one instrumental: no forceps	15 (1.2%)	1 (0.4%)	0.35	(0.05, 2.66)	0.31
SVD + CS	26 (2.0%)	8 (3.4%)	1.61	(0.72, 3.61)	0.25

Age at 1st delivery					
Under 20 years	174 (13.7%)	47 (19.7%)	*1.44*	*(1.00, 2.06)*	*0.049*
20–29 years	926 (72.9%)	174 (73.1%)	1.00		
30–49 years	170 (13.4%)	17 (7.1%)	*0.53*	*(0.31, 0.90)*	*0.018*
Total number of deliveries					
One	246 (19.4%)	39 (16.4%)	1.00		
2 to 4	978 (77.0%)	193 (81.1%)	1.25	(0.86, 1.81)	0.25
5+	46 (3.6%)	6 (2.5%)	0.82	(0.33, 2.06)	0.68
Occurrence of twins					
No	1254 (98.7%)	235 (98.7%)	1.00		
yes	16 (1.3%)	3 (1.3%)	1.00	(0.29, 3.46)	0.99
Time between deliveries					
One delivery	246 (19.4%)	39 (16.4%0	1.00		
All <2 years	167 (13.1%)	29 (12.2%)	1.10	(0.65, 1.84)	0.73
All greater than 2 years	608 (47.9%)	119 (50.0%)	1.24	(0.84, 1.83)	0.29
Mix of <2 and>2 years	249 (19.6%)	51 (21.4%)	1.29	(0.82, 2.03)	0.27
Type of perineal wound					
No Wound	442 (34.8%)	85 (35.7%)	1.00		
All Episiotomy	361 (28.4%)	51 (21.4%)	0.74	(0.51, 1.07)	0.11
At least one 3rd degree tear	5 (0.4%)	1 (0.4%)	1.04	(0.12, 9.01)	0.97
At least one laceration (no tear)	462 (36.4%)	101 (42.4%)	1.14	(0.83, 1.56)	0.43

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Presentation Number: 013

THE ICEBERG OF URINARY INCONTINENCE IN WOMEN

V. A. MINASSIAN, H. SUN, M. J. LICHTENFELD, W. F. STEWART;
Geisinger, Danville, PA.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To build the "Iceberg of Disease" in women with urinary incontinence **(UI)** by establishing prevalence estimates of the spectrum of disease from no UI in the population through significant UI in specialty care.

Background:
When women present to the pelvic floor specialist, their UI is fairly advanced and prevention has little impact. UI at its early stages could be reversible. Epidemiologic studies report prevalence estimates of as high as 50% in community dwelling women. However, paradoxically, only a minority of women seek or receive care for their UI.

Methods:
The General Longitudinal Overactive Bladder Evaluation - UI **(GLOBE-UI)** is a population-based study on the natural history of UI and its sub-types in women ≥40 years of age. GLOBE-UI participants were randomly selected and asked to fill the bladder health survey **(BHS),** a validated questionnaire on UI. Demographic information included age, body mass index (BMI), parity, marital status, and education. The BHS included 2 lifetime UI questions. Women who responded negatively to both questions or had insignificant symptoms were non-cases. Conversely, women who answered "yes" to the 2 UI questions, or those with significant UI symptoms were labeled as cases. Using data from the BHS and the electronic health record **(EHR),** we built the iceberg of disease. We established the 1st step by estimating the total number of women, ≥40 responding to the survey. The 2nd step of the iceberg was built by estimating the prevalence of UI among the responders. This was followed by the 3rd step representing the proportion of women with UI seeking care. Here, the numerator included women with a UI ICD-9 diagnosis. The 4th step included women receiving UI care (i.e., EHR documentation of anti-UI medication order, physical therapy or subspecialist referral, or CPT code for UI procedure). Finally, step 5 had only women from the 4th step seen in subspecialty clinic (i.e., urogynecology and female urology) (Fig. 1). Descriptive statistics were used to determine the prevalence estimates at all levels of the iceberg.

Results:
The estimated population pool of women ≥40 was 162,000. A random sample of 7,772 women received the BHS. Of those, 3,221 (41.4%) women responded. Prevalence of UI on the BHS was 1,326 (41.2%). Women with UI were a representative group of the baseline sample across all demographics except for BMI; about 80% of women with UI were overweight or obese versus 70% of the sample. Of all 1,326 women with UI, 344 (26%) reported having started urine loss 2 years ago or less, 353 (27%) had UI for 2–4 years, 218 (24%) had UI for 5–10 years, and 259 (20%) reported more than 10 years history of UI. In these women, distribution of mild, moderate, and severe UI was 25%, 50%, and 25%, respectively. Of all 1,326 women with survey-based UI

diagnosis, only 367 (28%) had a UI ICD-9 diagnosis in the EHR, 269 (20%) were receiving UI care, and 157 (12%) were referred to or were being cared for by a pelvic floor specialist (Fig. 1).

Conclusion:

About 41% of women in our population, 40 and older, have UI. The majority of these women have moderate or severe symptoms, and 75% have UI of 2 years duration or more. Less than 30% of women with UI seek care, and only about 12% are seen by a pelvic floor specialist. It is crucial not only to educate women, but also primary care providers about this highly prevalent yet treatable condition.

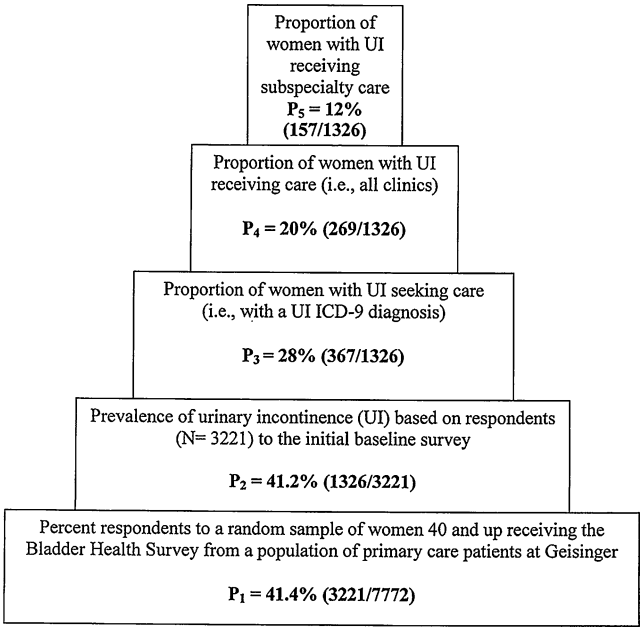

Figure 1: Iceberg of Disease in Women 40 Years of Age and Up

Presentation Number: 014

THE SOCIOECONOMIC ASSOCIATIONS OF FEMALE URINARY INCONTINENCE: RESULTS FROM THE UK 1958 BIRTH COHORT

R. CARTWRIGHT[1], V. KHULLAR[2], L. CARDOZO[3];
[1]Inst. of Reproductive and Dev.al Biology, Imperial Coll. London, London, United Kingdom, [2]Dept. of Urogynaecology, Imperial Coll. London, London, United Kingdom, [3]Dept. of Urogynaecology, King's Coll. Hosp., London, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To assess the socioeconomic associations of female urinary incontinence in a population based birth cohort.

Background:

At the population level, the major clinical and lifestyle risk factors for female urinary incontinence are consistently identified, and include age, parity, obesity, smoking, and a number of co-morbidities [1]. There remains however, conflicting evidence regarding the socioeconomic risks for incontinence, with studies variously reporting positive [2,3] or negative [4] associations with assorted measures of socioeconomic status.

Methods:

The 1958 Birth Cohort recruited all women born in the UK in a single week in 1958. Participants were followed up in 2008 at age 49–50, using a combination of interviewer administered and self-completed questionnaires. Diverse measures of socioeconomic status were recorded, including detailed assessment of household income, highest educational level, marital status, political preferences in the 2005 UK general election, and the National Statistics - Socioeconomic Classification (NS-SEC). This is an eight class socioeconomic coding, based on occupational status, and used in the UK National Census. Generic quality of life was measured using the SF-36 instrument. The reporting of "*any*" urinary incontinence was assessed using the item "Have you lost urine when you didn't mean to in the last year". Participants were asked whether this had caused problems in the last year, with "*bothersome"* urinary incontinence defined in this analysis by the response "Bothered me a lot". Logistic regression was used to test the contribution of each potential risk factor to "*any*" incontinence and "*bothersome*" incontinence. Parity, obesity, and smoking were adjusted for in each multivariate model. Analyses were conducted using SPSS v19.0.

Results:

4896 women were available for follow-up, of whom 98.6% responded regarding urinary incontinence. 1835 (36.9%) reported urinary incontinence within the last year. Among women with incontinence, 25.3% reported "a lot" of associated bother, and were more likely to record SF-36 scores <50% (adjusted OR 2.01, $p<.0001$). Using the NS-SEC system "*any*" incontinence was slightly more common for women with lower occupational status (unadjusted OR 1.03 per class; 95%CI 1.01–1.06; $p=.003$), but this effect was accounted for by adjustment for obesity, parity, and smoking (adjusted OR 1.01; 95%CI 0.99–1.04; $p=.261$). The effect was larger for "*bothersome*" incontinence (unadjusted OR 1.13 per class; 95%CI 1.08–1.17; $p<.0001$), with minimal attenuation after adjustment (adjusted OR 1.10; 95%CI 1.06–1.15; $p<.0001$). A similar pattern was seen for household income, with no significant association between monthly income (in £1000 increments) and "*any*" incontinence (adjusted OR 0.95, 95%CI 0.85–1.06, $p=.394$), but significant association with "*bothersome*" incontinence (adjusted OR 0.72, 95%CI 0.52–0.99, $p=.04$). Women of higher educational level were also less likely to report "*bothersome*" incontinence (adjusted OR 0.91 per category, 95%CI 0.87–0.95, $p<.0001$). Political preferences were also a significant predictor of incontinence. In unadjusted analyses left-wing Labour party voters (OR 1.22, $p=.012$), centrist Liberal Democrat partyvoters (OR 1.34, $p=.004$), and especially UK Independence Party voters (OR 2.32, $p<.0001$) were all at greater risk of "*any*" incontinence than right-wing Conservative party voters. Labour voters were also more likely to report "*bothersome*" incontinence (adjusted OR 1.44, 95%CI 1.04–1.94, $p=.02$).

Conclusions:

In this population based sample of perimenopausal women in the UK, urinary incontinence was common, but bothersome for less than 10%. Across a range of measures, women of higher socioeconomic

status were consistently less likely to report "*bothersome*" incontinence even after adjustment for confounders, but such associations were lacking for "*any*" incontinence. Previously conflicting reports of the socioeconomic associations of incontinence may therefore be explained by differences in the case definitions used. Limitations of this analysis include a lack of information about either incontinence type, or care seeking. Further research should assess whether these socioeconomic associations with bothersome incontinence relate to objective differences in incontinence severity, or are due to differences in subjective perception of leakage.

References:
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Presentation Number: 015

CAN URODYNAMIC STRESS INCONTINENCE BE DIAGNOSED BY ULTRASOUND?

K. NAZEMIAN[1], K. SHEK[2], A. MARTIN[2], H. DIETZ[2];
[1]Uppsala Univ. Hosp., Uppsala, Sweden, [2]Univ. of Sydney, Penrith, Australia.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Multichannel urodynamic testing is commonly used to diagnose urodynamic stress incontinence (USI) in women suffering from urinary incontinence. It has been claimed that USI may be diagnosed by imaging; others have disputed such claims. We determined the predictive value of ultrasound measurements for USI.

Background:
Translabial ultrasound (US) is increasingly used in the assessment of incontinent women. The combination of bladder neck descent (BND), urethral rotation and opening of the retrovesical angle (RVA) with bladder neck funnelling was originally identified on Xray cysto-urethrography as the anatomical correlate of stress urinary incontinence. These findings are common and quite striking (Fig. 1), but the predictive value of such findings for the diagnosis of urodynamic stress incontinence has, to the knowledge of the authors, never been defined.

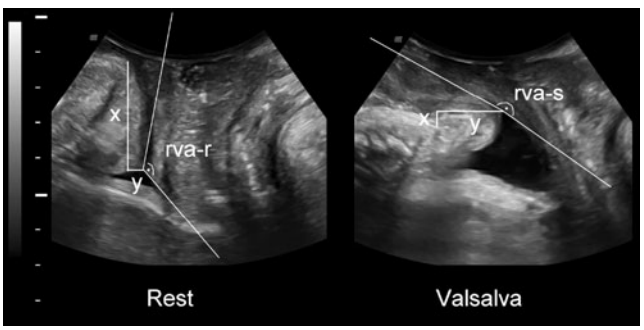

Fig. 1: Green Type II cystocele on US. BND (difference between measurement x at rest and on Valsalva)= 3.5 cm, urethral rotation= 60º, RVA= 182º.

Methods:
We retrospectively reviewed 277 patients seen at a urodynamic centre for interview, multichannel urodynamic testing, translabial 4D US (GE Voluson 730 expert and Voluson i systems) and clinical examination. Maximum urethral closure pressure (MUCP) was obtained with a perfused fluid-filled catheter using a freehand pull-through technique. Of 277 patients, 60 were excluded due to previous surgery. In four cases urodynamic testing was omitted, and another four ultrasound volume datasets could not be retrieved, leaving 209 datasets. All other reported data refers to this population.
Ultrasound analysis was performed by the first author, using proprietary software on a desktop PC, blinded against all other data. A test retest series (n=20) performed by the first and second authors showed excellent repeatability (ICC's between 0.87 and 0.95). Cohen's kappa for funnelling was 0.78 (95% CI 0.50–1.07). Agreement for the classification of Cystocele Green II between the first and second author was 100%. Cohen's kappa for Green type II cystocele with funnelling was 0.78 (0.50–1.07). Ethics approval had been obtained from the local Human Research Ethics Committee (reference 2011/04).

Results:
Average age was 54 (range 18–86) years, mean BMI 29.3 (17.3–50.1). Mean MUCP was 51 cmH2O (range 12–125). Urodynamic stress incontinence was documented in 151 patients (72%). Mean Oxford grading was 2.23 (0–5), 17% had avulsion defects. The mean retrovesical angle on Valsalva was 147 (72–217), Mean rotation was 73 (37–186), 49% of patients had funnelling on Valsalva. Mean BND was 31.5 (4.2–61.6)mm. 58% of patients were classified as Green type II cystocele, and 43% as Green type II cystocele with funnelling.

Table 1: Predictors of USI. Multivariate model includes MUCP and BND only

Predictor	OR	95% CI	P-Value
Age (years)	1.03	1.01–1.06	0.0065
Body Mass Index	1.03	0.98–1.09	0.2113
Puborectalis avulsion	1.47	0.63–3.43	0.3763
Modified Oxford Scale	1.14	0.89–1.47	0.2944
Retrovesical angle (Valsalva)	1.00	0.99–1.01	0.7595
Rotation of proximal urethra	1.01	1.00–1.02	0.0834
Bladder neck funnelling	1.54	0.84–2.82	0.1636
Max.urethral closure pressure			
Univariate	0.96	0.95–0.98	<.0001
Multivariate	0.96	0.95–0.98	<.0001
Bladder neck descent			
Univariate	1.05	1.02–1.07	0.0004
Multivariate	1.05	1.02–1.08	0.0005

Age, MUCP and BND were found to be statistically significant univariate predictors of USI using logistic regression (Table 1). MUCP and BND remained statistically significant when all variables were combined in a full multivariate logistic regression model (backwards elimination). Logistic regression was also used to examine the predictive value of Green type II cystocele with and without funnelling, adjusting for age, MUCP, BMI, and avulsion. A Green II cystocele with funnelling classification was found to increase the odds of USI by a factor of 2.5 (95% CI: 1.17–5.4, p=0.018).

Conclusions:
Translabial ultrasound can identify an anatomical configuration that is associated with USI, and our results confirm 40-year old radiological data. However, such imaging findings are relatively poor predictors and cannot replace conventional urodynamic testing.
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1.Ultrasound Obstet Gynecol. 2007;30(7):1002–6.
2. Int Urogynecol J. 2009;20(2):171–5.
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Presentation Number: 016

CAN URINARY NERVE GROWTH FACTOR (NGF) REPLACE URODYNAMICS TO DIAGNOSE LOWER URINARY TRACTS SYMPTOMS?

G. VIJAYA[1], R. CARTWRIGHT[2], G. DIGESU[1], A. DERPAPAS[1], P. GALLO[1], C. HENDRICKEN[1], R. FERNANDO[1], V. KHULLAR[1]; [1]ST MARY'S Hosp., LONDON, United Kingdom, [2]Inst. OF REPRODUCTIVE AND DEVELOPMENTAL BIOLOGY, IMPERIAL Coll., LONDON, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of our study was to compare urinary NGF levels with lower urinary tracts symptoms (LUTS) and urodynamic diagnosis.
Background:
NGF is one of the neurotrophic factors released by urothelium and smooth muscle. NGF levels has been found to be increased in LUTS such as overactive bladder, interstitial cystitis, bladder outlet obstruction (BOO) and bacterial infection in both animal and human studies. However the validity of urinary NGF as a diagnostic biomarker in women with LUTS is still unclear [1–3]
Methods:
Women with LUTS were recruited from a tertiary referral urodynamics clinic. Ethical approval was obtained from the local REC committee and written consent was obtained. The exclusion criteria were history of moderate or severe pelvic organ prolapse, neurological condition, voiding dysfunction and urinary tract infection.
All eligible women completed a three day frequency-volume chart, a King's health questionnaire and underwent urodynamics. Dual channel cystometry was performed with each woman supine and the bladder filled through a 10 F filling catheter; a fluid-filled 4.5 F catheter was used to measure the intravesical and abdominal pressures. The bladder was filled with room-temperature saline at 100 mL/min. The filling catheter was removed when the patient developed a strong desire to void or 500 mL had been infused into the bladder. Provocative manoeuvres were used with each woman in a standing position. Women were asked to cough 1, 3, and 5 times with maximal effort and then listen to running water and wash their hands in cold water. Finally, they were seated for a pressure-flow study that was performed in private.
A midstream specimen of urine was collected prior to urodynamics and immediately centrifuged at 3000 rpm at 4°C for 10 min About 3 ml of urine was also sent to measure urine creatinine. The centrifuged supernatant urine was then frozen at −80°C and used to measure the urinary NGF levels by ELISA using the NGF E max Immuno assay system (Promega Madison WI). The total urinary NGF levels were further normalized to the concentration of urinary creatinine (NGF/Cr level).Urine samples from asymptomatic volunteers who did not have any LUTS were also processed to measure the NGF levels.
Urinary NGF levels between different urodynamic diagnoses and between symptomatic and asymptomatic women were compared using the one way ANOVA with Bonferroni correction and the Mann Whitney *U* test respectively.
Results:
A total of 168 patients (141 symptomatic women and 27 asymptomatic women) were studied.
There was a statistical significant difference in NGF levels between asymptomatic women and women with LUTS (p value <0.001, Mann Whitney test) and there was no statistical significant difference in NGF levels between women with OAB and non OAB symptoms p value >0.05, Mann Whitney test) as shown in table1. There was a statistical significant difference in the NGF levels in relation to the severity of daytime frequency, nocturia,urgency,urge urinary incontinence and stress urinary incontinence (one way ANOVA with Bonferroni correction, P value <0.05). There was no significant difference in mean NGF levels between the different UDS diagnosis (one way ANOVA with Bonferroni correction, P value >0.05), as shown in table 2.

Table 1

	Controls (*n*=27)	Symptomatic for LUTS (*n*=141)	non-OAB (*n*=12)	OAB (*n*=129)
Mean NGF (±SD)	0.076 (±1.38)	4.24 (±7.39)	3.41±4.95	4.31±7.58
	P<0.001	*P*>0.05		

Table 2

Diagnosis	Total number	Mean NGF (SD)
CONTROLS	27	0.076 (±1.38)
DO	60	4.47 (±7.74)
USI	16	2.71 (±2.88)
DO and USI	29	6.28 (±10.1)
PAINFUL BLADDER & REDUCED BLADDER CAPACITY	36	2.73 (± 5.13)

Conclusions:
Urinary NGF levels are significantly increased in women with LUTS compared to asymptomatic controls. However NGF failed to differentiate between the different urodynamic diagnoses. Therefore urinary NGF levels are not a reliable biomarker to discriminate between different urodynamic abnormalities.

References:
1. BJU Int 2008; 102:1440–1444
2. J Urol. 2006 May; 175(5):1773–6;
3. Neurourol Urodyn. 2007; 26(3):405–9

Presentation Number: 017

HOW DO UROGYNAECOLOGIST TREAT FAILED SUBURETHRAL SLINGS? EXPERIENCE FROM THE BRITISH SOCIETY OF UROGYNAECOLOGY DATABASE AND LITERATURE REVIEW:

A. PATIL;
Medway NHS Fndn. Trust, Gillingham, UK, Gillingham, Kent, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to review the British Society of Urogynaecology (BSUG) database of continence procedures performed till January 2010 to determine what surgical treatments have been used for persistent or recurrent SUI after a failed mid-urethral sling (MUS).

Background:
MUS procedures have high success and satisfaction rates. However, a small percentage of MUS operations will fail and most centres have limited experience of treating this outcome. Hence, the treatment of recurrent or persistent SUI after failed MUS is a new dilemma for the Urogynaecologist and urologist.

Methods:
We reviewed the available BSUG data submitted before January 2010, of which 97% of the data was entered after 1st January 2007. Total 14,977 surgical procedures for incontinence or prolapse were logged into the database by 68 centres in the U.K. Women who underwent a repeat anti-incontinence surgery for persistent USI after failed MUS were included in the cohort. Women who had previous slings with concomitant prolapse repairs were excluded because a prolapse repair may alter urinary symptoms, independent of the MUS. This cohort then was then divided into four groups depending upon the type of slings they underwent as a primary procedure: retro-pubic MUS, TVT-obturator MUS (TVT-O), transobturator MUS (TOT-outside in) and short single incision sling (mini-slings). Various demographic data was collected for each group and the repeat treatment noted. Outcome data was described where available.

Results:
Out of total 313 failed MUS procedures, the commonest second surgical intervention was a repeat retropubic MUS and was used in 54% (170/313) of repeat procedures (table 1.). Bladder neck injections were the second commonest repeat procedure (43/313 cases: 14%). TVT-Os were used as a repeat procedure in 12% (38/313) and TOTs in 8% (25/313). Small numbers of colposuspensions (20/313 - 6%) and Aldridge slings (6/313 - 2%) were also used.

Conclusion:
Persistent or recurrent SUI after previous failed MUS poses a new challenge for surgeons. The present study suggests that the retropubic TVT seems to be the preferred choice for the management of such cases probably due to familiarity, its effectiveness, minimal invasiveness, low complication and morbidity rates as a primary procedure.
Although this study provides an excellent description of current practice in a multicentre context, there is little information on success rates due to poor outcome data. Better insight into the best treatment option may only be obtained when good quality outcome data is provided. Future audit needs to concentrate on encouraging teams to supply full datasets.

Table 1:

Original procedure:	TVT:	TVT-O:	TOT :	TVT-S:
Repeat procedure				
TVT	54	24	72	20
TVT-O	32	–	–	6
TOT	12	4	8	1
TVT-S	–	8	–	–
BNI	25	4	12	2
COLPOSUSPENSION	16	4	–	–
ALDRIDGE SLING	6	–	–	–
LAP URETHROPEXY	2	–	–	–
AR + BNB	1	–	–	–

Lap: laparoscopic, AR : anterior repair, BNB : bladder neck buttressing

Presentation Number: 018

TOMOGRAPHIC IMAGING OF THE PELVIC FLOOR IN NULLIPAROUS WOMEN: LIMITS OF NORMALITY

T. ADISUROSO[1], K. SHEK[2], H. DIETZ[2];
[1]SYDNEY Med. SCHOOL - NEPEAN Univ. OF SYDNEY, PENRITH NSW, Australia, [2]SYDNEY Med. SCHOOL NEPEAN, Univ. OF SYDNEY, PENRITH NSW, Australia.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
This study was performed to determine the limits of normality for tomographic ultrasound imaging (TUI) of the puborectalis muscle.

Background:
Avulsion of the puborectalis muscle has been found in 13–36% of women after a first vaginal delivery(1). This injury is a risk factor for pelvic organ prolapse (2). Several diagnostic methods have been proposed, with TUI probably the most repeatable(3). Our aim was to define normal appearances of the puborectalis muscle on TUI.

Methods:
This is a sub- analysis of the datasets of 497 pregnant nulliparous women recruited for two studies. All participants were carrying a singleton pregnancy at a mean gestation of 36.4 weeks. All had

undergone an interview and 4D translabial ultrasound, the latter after voiding, and in lithotomy. We acquired volume data at rest, on maximum Valsalva and pelvic floor contraction (PFMC). Volume datasets were analyzed with the help of proprietary software.

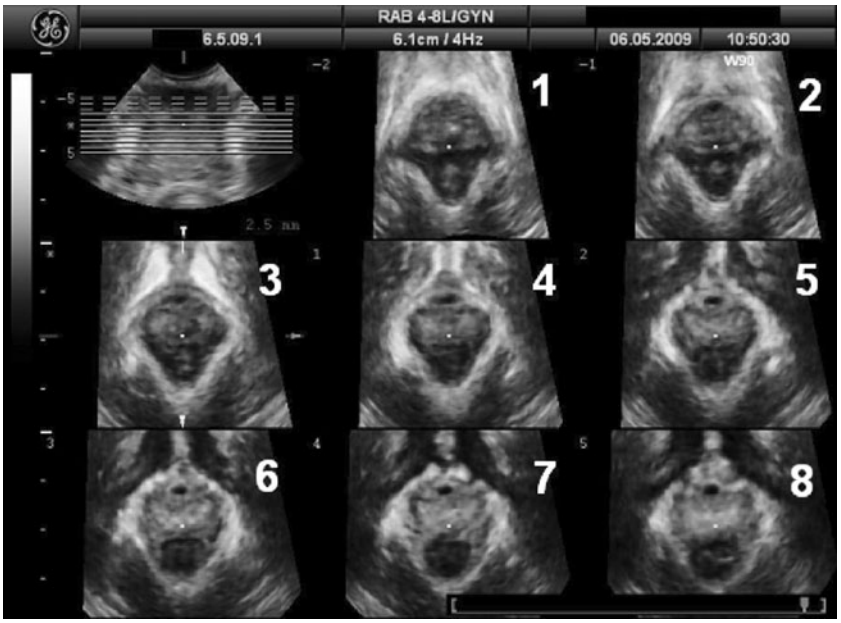


Figure 1: "Abnormal" insertion of the puborectalis muscle in Slice 1 and 2 in a nulliparous pregnant woman, a relatively common finding.

TUI (see Fig.1) was performed on volumes obtained at PFMC at 2.5 mm slice intervals, from 5 mm below to 12.5 mm above the plane of minimal hiatal dimensions, producing eight slices per patient(3). Slices were scored as normal or abnormal, separately for right and left. In a test retest series on 20 datasets, a Cohen's kappa of 0.66 for scoring abnormal insertions was obtained.

Results:

Of 497 volume datasets, 495 could be analysed. Mean age was 28 (range 18–45). Mean pre-pregnant BMI was 24.7 kg/m2 (range, 15.1–47.1). Mean bladder neck descent on Valsalva was 21.2 (range 0.9–53.7)mm. Abnormalities of the insertion of the puborectalis muscle were commonly seen in slices 1 and 2, but were uncommon in slice 3 (<8%), very uncommon in slice 4 (1%), and rare elsewhere. Considering our minimal criteria for diagnosing a full avulsion of the puborectalis muscle (slices 3–5 abnormal), the diagnosis of a full avulsion was made in three out of 495 nulliparous women. On reviewing those three cases, two were false positive as judged by the two senior authors. However, one was judged to be abnormal by both senior authors, with a full avulsion diagnosed on the left.

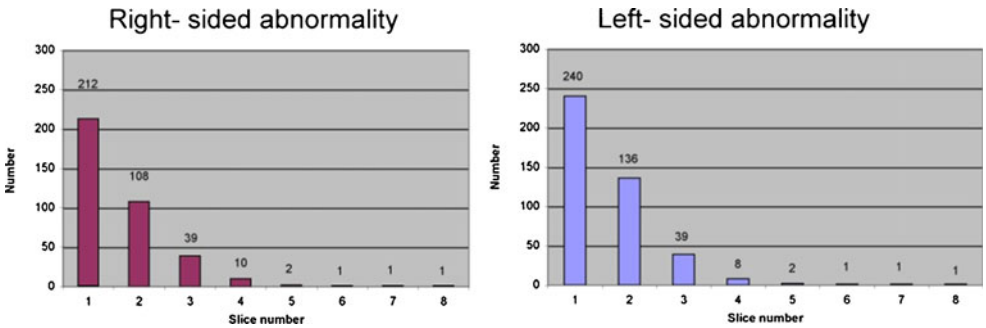


Fig. 2: Histograms showing the number of women with a right-sided (left) or left-sided (right) 'defect' in slices 1 to 8.

Conclusions:
In this group of pregnant nulliparous women, 'abnormalities' of the puborectalis muscle insertion were commonly observed in the lower 2 slices, i.e. 5 and 2.5 mm below the reference plane. This is explained by the non-Euclidean, i.e. warped nature of the true hiatal plane. Our minimal diagnostic criteria for levator avulsion (3) were fulfilled in 3/495 women (0.6%), two of which were obvious false- positives.
This study supports the use of the plane of minimal hiatal dimensions and slices 2.5 and 5 mm cranial to that plane as minimal diagnostic criteria for puborectalis muscle avulsion. The likelihood of a false positive diagnosis seems very low.

References:
1. Br J Obstet Gynaecol. 2010;117:1485–92.
2. Br J Obstet Gynaecol. 2008;115:979–84.
3. Int Urogynecol J. 2010;DOI 10.1007/s00192-010-13294

Presentation Number: 019

URINARY SYMPTOMS AND URODYNAMIC FINDINGS IN WOMEN WITH PELVIC ORGAN PROLAPSE: IS THERE A CORRELATION? RESULTS OF AN ARTIFICIAL NEURAL NETWORK ANALYSIS

M. SERATI, **S. SALVATORE**, G. SIESTO, E. CATTONI, A. BRAGA, P. SORICE, A. CROMI, F. GHEZZI, P. BOLIS;
Univ. of Insubria, Varese, Italy.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
Aim of our study was to assess the correlation between urinary symptoms and urodynamic findings, in women with pelvic organ prolapse (POP).

Background:
The recommendations from the International Continence Society (ICS) and the International Consultation on Incontinence (ICI) clearly stated that the urodynamic (UDS) evaluation in the pre-operative workout of women scheduled for POP repair is mandatory before surgery . The pre-operative UDS might be useful not only to unmask occult urodynamic stress incontinence, and thus addressing patients to specific surgical procedures if needed, but also to identify women with concomitant Detrusor Overactivity (DO) who could also subsequently need the administration of antimuscarinic drugs. Nevertheless, the cost-effectiveness of pre-operative UDS is still issue of matter since the UDS findings rarely affect the clinical decision-making in terms of choice of POP reconstructive procedures.

Methods:
A cross-sectional observational study was performed, enrolling consecutive women seeking cares for POP, who underwent clinical and urodynamic evaluation. Data regarding baseline characteristics, symptoms, anatomical and urodynamic findings were gathered for each patients. All methods, definitions and units were conforming to the standards jointly recommended by the ICS. Multivariate analyses (MLRs) and Artificial Neural Networks (ANNs) were performed to design predicting models.

Results:
A total of 802 women with POP were included. POP-Q stages and baseline data poorly correlated to final UDS findings. Stress urinary incontinence (SUI) and overactive bladder (OAB) were both independently associated to each UDS diagnosis, including DO, urodynamic stress incontinence (USI) and mixed urinary incontinence (USI + DO) (tables). ROC comparison confirmed that ANNs were more accurate than MLRs in identifying predictors of urodynamic diagnosis, but none of this method could successfully overcome UDS

Conclusions:
In agreement with previous papers, in this series the ROC comparison also confirmed that the ANNs were more accurate than MLRs in discriminating variables involved in the final UDS diagnosis. However, despite the sophisticate statistical method adopted, most reported associations between baseline data, symptoms, anatomical findings and UDS diagnosis, even if statistically significant, are definitely clinically useless: indeed symptoms as stress incontinence and OAB were commonly recorded, and actually complained, as independent predictors of all the UDS diagnosis investigated, and mostly in association. In addition, also in our model, only few associations were found between anatomical descent and UDS findings.
Despite the current subject of debate based on the actual utility of UDS in women with POP, even the implementation of ANN, a sophisticated computer-based technology, does not permit an accurate diagnosis just on the basis of symptoms, avoiding urodynamics. Therefore in women with POP, especially if scheduled for surgery, UDS should be considered mandatory, since misleading counseling could carry to unpleasant unexpected events.

Table 1: Multiple logistic regression of demographic variables potentially affecting Urodynamic findings.

	Normal UDS	Pure DO	USI	Mixed	Any DO	Any USI
Age (years)	NS	1.03 (1.02–1.05)	0.98 (0.96–0.99)	0.98 (0.96–0.99)	NS	0.97 (0.95–0.98)
BMI (kg/m^2)	NS	NS	NS	0.95 (0.91–0.99)	0.95 (0.92–0.98)	NS
Menopausal	NS	NS	NS	NS	NS	NS
HRT	NS	0.53 (0.30–0.96)	NS	NS	0.65 (0.43–0.98)	NS

Table 2: Multiple logistic regression of obstetrics and gynecological variables potentially affecting Urodynamic findings.

	Normal UDS	Pure DO	USI	Mixed	Any DO	Any USI
Vaginal deliveries	NS	NS	NS	NS	NS	NS
Macrosome	NS	NS	NS	NS	NS	NS
Operative delivery	NS	NS	1.69 (1.05–2.73)	NS	NS	NS
Prior Hysterectomy	NS	NS	NS	NS	NS	NS

Table 3: Multiple logistic regression of anatomic variables potentially affecting Urodynamic findings.

	Normal UDS	Pure DO	USI	Mixed	Any DO	Any USI
POP Stage I	1.94 (1.30–2.88)	NS	NS	NS	NS	NS
POP Stage II	NS	NS	NS	NS	NS	NS
POP Stage III–IV	NS	1.75 (1.03–2.96)	NS	2.10 (1.28–3.45)	2.51 (1.68–3.75)	NS

Table 4: Multiple logistic regression of urinary incontinence symptoms potentially affecting Urodynamic findings.

	Normal UDS	Pure DO	USI	Mixed	Any DO	Any USI
SUI	1.91 (1.30–2.79)	4.41 (2.87–6.78)	2.70 (1.88–3.87)	2.11 (1.39–3.20)	1.57 (1.11–2.22)	4.94 (3.50–6.98)
OAB wet/dry	1.90 (1.31–2.74)	3.29 (1.95–5.54)	2.01 (1.44–2.82)	1.94 (1.26–2.97)	2.92 (2.04–4.18)	NS
Voiding dysfunction	NS	NS	NS	NS	NS	NS

Presentation Number: 020

IS THERE LIGHT AT THE END OF THE TUNNEL? THE USE OF NEAR INFRARED SPECTROSCOPY TO DETECT DETRUSOR OVERACTIVITY IN WOMEN WITH AN OVERACTIVE BLADDER

H. MASTOROUDES, I. GIARENIS, M. VELLA, D. ROBINSON, L. CARDOZO, I. KARROUZE;
King's Coll. Hosp., London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: Yes

Objective:
The aim of this study was to evaluate Near Infrared Spectroscopy (NIRS) as a noninvasive alternative to filling cystometry for detecting detrusor overactivity in women with overactive bladder.
Background:
Overactive bladder is a common and troublesome condition which significantly affects quality of life. Filling cystometry is usually employed to diagnose detrusor overactivity which is found in 64% of patients with overactive bladder (1). Near-infrared spectroscopy is a non-invasive, real time optical technological method used to detect changes in oxygenation in oxy-haemoglobin, deoxy-haemoglobin and total haemoglobin levels. Its use has been applied to many disciplines as a research tool especially where ischaemic conditions require evaluation (2). NIRS has previously been shown to be useful in the study of physiological changes occurring in the bladder during filling and emptying (3). Detrusor overactivity may cause local vascular and haemodynamic changes which could be detectable by NIRS.
Methods:
This was a prospective study of patients who had symptoms of overactive bladder recruited from a tertiary referral urogynaecology clinic. All patients had videocystourethrography (VCU) with simultaneous NIRS. A transcutaneous self-adhesive patch was placed 2 cm above the pubic symphysis to which an emitter and sensor for NIRS were connected. The evaluation was commenced in the supine position and patient movement was restricted during the test to prevent interference. The results of these two methods were compared and analysed by two separate teams. The assessor of the NIRS was blinded to the urodynamic diagnosis. Each team reported whether detrusor overactivity was present and if so at which times. The timings of detrusor events were compared and analysed for correlation. In those with severe detrusor overactuvity on cystometry, the NIRS trace was scrutinized for equivalent changes. Ethical approval was obtained
Results:
Overall 100 female patients were recruited of whom 95 were evaluable. The mean age was 34 years (range 24–86) and the mean BMI 27.9 kg/m2 (range 18.6–46.7). In 6.3% (6/95) of cases, NIRS analysis was difficult as the assessor was unsure whether

changes were related to valsava maneuvere interfernces or secondary to detrusor overactivity. In 2% (2/95) of cases there was equipment failure or NIRS patch disconnection. The results are shown in the Table 1.

Table 1 Comparison between VCU and NIRS in diagnosis of Detrusor Overactivity (DO)

VCU	DETRUSOR OVERACTIVITY	NO DETRUSOR OVERACTIVITY	
NIRS			
DETRUSOR OVERACTIVITY	25 (26%)	46 (48%)	71
NO DETRUSOR OVERACTIVITY	6 (6%)	18 (19%)	24
TOTAL	31	64	95

Of the cases where detrusor overactivity was detected by both methods of analysis, only in 32% (8/25) was there correlation between detrusor overactivity periods on NIRS and the cystometric trace. The sensitivity of NIRS was 80.6% with a specificity of 28.1%. The positive predictive value was 35.2% and the negative predicative value 75%. There was no correlation between the size of detrusor contractions and the presence of NIRS changes.

Conclusions:

Whereas NIRS has been shown to be useful, particularly in bladder outflow obstruction in males, this study would suggest it is an unreliable method for detecting detrusor overactivity in women with overactive bladder symptoms. Further studies are required to ensure correct interpretation and refinement of NIRS analysis and results.

References:

(1)J Urol; 175:191–195
(2)Clin Physiol & Fun Im 2002;22(3):1–8
(3)Canadian journal of urology; 15(6) Dec 2008

Presentation Number: 021

IMPAIRED DETRUSOR CONTRACTILITY AND SURGICAL TREATMENT FOR STRESS URINARY INCONTINENCE

L. C. MENGHEANG[1], **S. G. FLETCHER**[2], K. SATHYAMOORTHY[1], R. GONZALEZ[2];
[1]Baylor Coll. of Med., Houston, TX, [2]The Methodist Hosp., Houston, TX.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

Our aim with this study was to evaluate impaired detrusor contractility on urodynamic studies prior to synthetic mid urethral sling surgery. We then sought to identify a direct relationship between (IDC) and two specific outcome measures at 6 weeks after surgery: 1) urinary retention requiring clean intermittent catheterization and 2) de novo lower urinary tract symptoms at 6 weeks after surgery.

Background:

Little conclusive data exists regarding urodynamic (UD) variables predictive for voiding dysfunction after synthetic midurethral sling (MUS) surgery. Previous studies have reported a low detrusor contraction during voiding or valsalva voiding to be associated with urinary retention, the need for clean intermittent catheterization (CIC) or de novo lower urinary tract symptoms (LUTS) after stress incontinence surgery. Those reports were for Burch and autologous fascia pubovaginal sling procedures. Various outcome measures and follow up time points have been described, making data comparisons difficult. No published studies have examined these factors specifically in the setting of the synthetic mid urethral sling.

Methods:

Retrospective chart review was performed for all synthetic midurethral sling procedures at a single institution from 1/1/2010 to present. Subjects with complete pre-operative UD records and a minimum 6-week follow up were included in the study. Those with concomitant prolapse surgery were not excluded. IDC pre-op was defined as Pdet Qmax<10 cm/H_2O. The primary outcome measure was urinary retention requiring CIC or re-operation at 6-week follow up. The secondary outcome measure was de novo LUTS at 6 week follow up. Categorical analysis using the Chi square statistic was performed to calculate the odds ratio regarding a primary or secondary outcome in relation to Pdet Qmax<10 cm/H_2O.

Results:

108 patients underwent MUS from January 2010 to present. 78 patient charts contained complete UD and≥6 week follow up. Average patient age was 54.4 years (range 32–87). Sling procedures performed were: TOT (n=57), SPARC (n=9), TVT (n=6), and MiniArc (n=6). Concomitant surgeries were: hysterectomy (n=14), anterior repair (n=21), posterior repair (n=12), vault suspension (n=8). Pre-op UD identified 16 (20.5%) patients with IDC. At 6-week follow up, there were no patients in urinary retention, requiring CIC or reoperation. A total of 10 subjects (12.8%) reported de novo LUTS, with 3 from the IDC group. The odds ratio for IDC and de novo LUTS was 0.633 (p=0.334). Of the 3 patients with IDC, none demonstrated a Qmax<20 mL/sec. Conversely, of the 16 patients with IDC, 6 subjects had a Qmax <20 mL/s, but none experienced any negative study outcome.

Conclusions:

Impaired detrusor contractility does not appear to be a risk factor for post-op urinary retention or reoperation after MUS. LUTS was seen post-op in the IDC group, but there was no significant odds relationship between IDC and LUTS. The small study size is a limiting factor, and a larger investigation is planned. This study

suggests that IDC will join the ranks with other UD variables that have little predictive value for outcomes after MUS.

Presentation Number: 022

MANAGEMENT OF ANTERIOR AND APICAL PROLAPSE, STAGE III-IV, WITH SACROSPINOUS TRANSVAGINAL MESH. (ELEVATE ANTERIOR & APICAL®). 12 MONTHS FOLLOW UP

V. BOSQUE, J. RIVERO.C, C. MANTELLINI, G. LOPEZ; Centro Med. Docente La Trinidad, Caracas, Venezuela, Bolivarian Republic of.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate the efficacy and safety of the apical and anterior transvaginal mesh with sacrospinous anchoring (Elevate anterior & apical ® AMS,Minnetonka,MN,USA) in repairing pelvic organ prolapse (POP).

Background:
We included in this study 29 patients with anterior and/or apical POP, stages III or IV based on POPQ classification that consulted our Pelvic Floor and Minimally Invasive Surgery Clinic in which we did the POP repair using the anterior/apical mesh with transobturator and sacrospinous anchoring (Elevate anterior & posterior ® a Poliprolilen-Inte Pro lite, Type I mesh, with 2 anterior fixation tips for obturator anchoring and 2 posterior apical fixation tips for sacrospinous anchoring with needle kit).

Methods:
This is a descriptive prospective study. All the patients included in this study were followed up at 1, 3, 6 and 12 months after surgery, except one. The variables measured were efficacy, determined with a POPQ results equal or less than −1, and recurrence measured as needing reoperation. Safety was determined by device related complications; registry and measuring quality of life improvement using the PFDI-20 and PFIQ-7 forms. The quantitative data has been presented using median test +−SD. The preoperative data regarding quality of life were compared with the postoperative data at 1, 3, 6 and 12 months follow up visits using the paired *t*-test. The p values were statistical significant if they were <0, 05 and highly significant if they were <0, 01. It was used the Statistical Package for the Social Sciences (SPSS 16).

Results:
Before surgery 31.03% of the patients were presenting cistocele, 41.37% apical prolapse or hysterocele and 27.58% both anterior and apical prolapse. After 12 months follow up period. 28 patients completed 12 months follow up (96.55%). The efficacy rate was 100% in the anterior prolapse group, 91.66% in the apical prolapsed group and 100% in the apical/anterior prolapse group. In 22 patients we used a TOT (Monarc®) for treatment of the additional urinary stress incontinency. We had 2 complications, an abdominal wall hematoma that was managed with local compression and a 6,89% extrusion rate (2 cases) both managed in office setting. We observed a statistical significant improvement on quality of life (p<0,01) with a reduction of 78,1% y 81,7% in PFDI-20 y PFIQ-7 results respectively.

Conclusions:
Elevate anterior & apical ® is a efficient device for repairing level I-II of vaginal support, improving quality of life with low rate of complications and recurrence in a 12 months follow up period. Its success and quality life improvement rates are similar of other authors results using sacrocolpopexia. It is high effective in the repairing of total POP with low complications and recurrence rates. It is necessary to do similar studies with greater follow up periods to observe if this rates maintain in time.

Presentation Number: 023

TWO YEAR CLINICAL OUTCOMES OF A TROCAR-GUIDED TRANSVAGINAL MESH REPAIR UTILIZING A NEW LIGHT-WEIGHT SYNTHETIC MESH

A. L. MILANI[1], V. LUCENTE[2], C. URQUHART[3], P. HINOUL[4], M. COSSON[5];
[1]Reinier de Graaf Group, Delft, Netherlands, [2]The Inst. for Female Pelvic Med. & Reconstructive Surgery, Allentown, PA, [3]Johnson & Johnson Med. Ltd, Livingston, United Kingdom, [4]Ethicon Inc, Somerville, NJ, [5]CHRU de Lille, Hôpital Jeanne De Flandre, Lille, France.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:
To evaluate the durability of outcomes following a partially resorbable transvaginal mesh repair at two years following surgery.

Background:
There is increasing evidence that transvaginal mesh for vaginal prolapse repair reduces the anatomical recurrence rates. A partially absorbable mesh of 31 g/m^2 has replaced the conventional polypropylene mesh (45 g/m^2). This study aims to assess whether these new mesh characteristics would still provide the same anatomic support as the mesh in the original polypropylene mesh device. One year results provided evidence that this transvaginal mesh repair was safe and led to improved anatomic and functional outcomes[1]. Here we report 2 year outcomes from this study.

Methods:
This is a prospective multi-centre cohort study. Women with Stage III and IV pelvic organ prolapse gave written informed consent to participate in this study. All participants underwent the standardized trans-vaginal mesh placement using a partially absorbable mesh (Gynecare Prolift + M™ Pelvic Floor Repair System, Ethicon, NJ). Anatomic outcomes were assessed using the POP-Q scale, defined as anatomic success POP-Q Stage≤1 in the treated compartment, without further surgical re-intervention for POP. Patient Reported Outcomes included the Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7) and PISQ-12. Adverse events were collected.

Results:
There were 128 enrolled women of which 127 underwent the study procedure. Mean age was 63.9 years. 81.9% had Stage III, 15.0% Stage IV and 3.1% had a Stage II prolapse in the treated compartment. Forty-one women (32.3%) underwent an anterior mesh repair, 16 women (12.6%) a posterior and 70 women (55.1%) a total pelvic floor repair. Twenty-one patients (16.5%) had a concurrent hysterectomy and 36 (28.3%) a mid-urethral sling.

At 2 years, 35.2% and 39.3% were Stages 0 and I in the treated compartment, respectively; 20.5% were Stage II and 0.8% Stage III. The proportions of patients with leading edge above the hymen, in the treated compartment at 24 months, are detailed in Table 1. Five patients (4.1%) had surgical re-intervention for prolapse in the treated compartment; 3 within one year, and 2 between 1 and 2 years post-surgery. Two patients had surgery to repair a previously untreated compartment.

At 1 year, 13 patients (10.2%) reported mesh exposure, by 24 months the cumulative number had risen to 16 patients (12.5%). Ten of these exposures required partial mesh excision. Concurrent hysterectomy was performed in five of the patients with mesh exposure, and one had concurrent sacrospinous ligament fixation.

Significant ($p<0.001$) improvements from baseline scores for PFDI-20, POPDI and PFIQ-7 were observed at 1 and 2 years (Table 2). There was a statistically significant ($p<0.001$) improvement in sexual function score (PISQ-12) in sexually active patients from baseline to at 12 months, which was sustained at 2 years. At baseline, dyspareunia was reported in 18/61 (29.5%) sexually active patients. At 24 months, 10 of these 18 patients reported resolution of dyspareunia; 2 had ongoing dyspareunia, 1 patient had not returned to sexual activity for unrelated reasons and 4 patients did not provide sexual activity data. One patient had pre-existing dyspareunia at baseline which resolved at 12 months and recurred at 24 months; one patient reported de novo dyspareunia at 12 and 24 months. Five (7.6%) patients of the 66 patients, who were not sexually active at baseline, resumed sexual intercourse without de novo dyspareunia.

Conclusion:
The results of this study suggest sustained, good anatomic support by using a partially resorbable mesh consistent with the original polypropylene mesh, and demonstrate high patient satisfaction and functional improvements. No apparent safety concerns appeared with the change in mesh. The low rate of *de novo* dyspareunia together with the improvement sexual function score is encouraging.

References:
[1]Am J Obstet Gynecol. 2011 Jan;204(1):74.e1–8. Epub 2010 Oct 20.

Table 1: Anatomic Outcomes

Leading Edge	Baseline (n=127)	24 Months (n=122)
−3 cm	0	43 (35.2%)
−2.5 to −1.5 cm	0	48 (39.3%)
−1 to −0.5 cm	0	14 (11.5%)
0	0	6 (4.9%)
+0.5 to +1 cm	4 (3.1%)	5 (4.1%)
+1.5 to +2 cm	57 (44.9%)	0
+2.5 to +3 cm	28 (22.0%)	1 (0.8%)
>+3 cm	38 (29.9%)	0
Re-intervention	0	5 (4.1%)
Success rate (Leading edge within the hymen)% (95% CI)		86.1% (78.6–91.7)

Data presented as numbers (%)

Table 2: Patient Reported Outcomes

n=127	Baseline	12 months	24 months
PFDI-20	98.9 (52.0)	25.9 (28.1)	28.8 (29.2)
POPDI sub score	41.4 (21.9)	6.4 (9.9)	7.2 (10.5)
PFIQ-7	74.5 (70.5)	9.5 (23.4)	12.5 (30.3)
PISQ-12 (n=60)	33.4 (7.8)	39.3 (4.1)	39.1 (4.5)

Data presented as mean (± SD) and n (%). PFDI-20 & PFIQ-7 scores range from 0 (best) to 300 (worst);

POPDI score range from 0 (best) to 100 (worst). PISQ-12 scores range from 0 (worst) to 48 (best)

Presentation Number: 024

LONG-TERM RESULTS OF MESH TROCAR-GUIDED SURGERY IN RECONSTRUCTION OF PELVIC ORGAN PROLAPSE

M. KRCMAR, L. KROFTA, J. FEYEREISL, M. OTCENASEK, K. DLOUHA, E. KASIKOVA;
Inst. for the Care of Mother and Child, Prague 4, Czech Republic.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
The aim of this prospective study was to assess long term outcome (5–6 years) of the trocar-guided mesh surgery to correct POP by the vaginal approach.
Background:
The use of vaginal synthetic mesh procedures to correct pelvic organ prolapse (POP) has become widespread. There is still lack of studies evaluating long-term outcomes and complications of these procedures.
Methods:
This is an open, prospective, observational study of patients operated with the Prolift™ technique at one center between June 2005 and December 2010. A total number of 213 women were included in the study during this period. Overall, 61 patients have been operated during 2005 and 2006 with drop-out of 8 patients (13%) for follow-up. The pre- and postoperative evaluation (1 month, 3 months, 6 months, 1 year and once per year) comprised of a vaginal examination with the grading of the defect according to the POP-Q system of the ICS, completing PFDI, PFIQ, ICIQ and PISQ questionnaires and MRI scan before and after the procedure. Patients self-evaluated the severity of their symptoms with the use of a visual analog scale (VAS) ranging from 0 to 10. All the patients had stage 2 or greater POP-Q prolapse preoperatively. The surgical procedures were: total Prolift—20 (37.8%), anterior Prolift 13 (24.5%) and posterior Prolift repair 20 (37.8%). Overall, 43 (81%) women had a prior hysterectomy and 47 (89%) had a previous POP surgery. Concurrent procedures were not performed. For statistical evaluation paired *t*-test with 95% confidence interval has been used.
Results:
The mean age was 60.6 years (32–84), mean BMI 25.6 (20.2–39,3) kg/m^2, and mean parity was 2.5 (1–8). The mean operating time was 73,1 min (20–135), and mean blood loss 83,77 ml (20–250). There was one (0,53%) major peroperative complication: bladder perforation recognized during surgery. There were no other complications such as urethral, nerve or bowel injury or serious bleeding. Early postoperative complications (day 0–7): urinary tract infection-1 (0,53%), febrile morbidity-0%, deep hematoma-0%, urinary retention-0%.
After 6 and 5 years follow-up of those patients 44 women (83%) were anatomically cured of prolapse, whereas 9 (27%) women had a POP defect≥Gr. II. However 6 (11.3%) had the recurrent defect, while 3 (5.7%) patients developed symptomatic POP on the opposite side of the previously well-supported compartment. In the anatomically cured group, where mesh was inserted only in the anterior compartment, we found statistically significant changes in POP-Q points: Aa, Ba, C and D. Points Ap, Bp, TVL, gh and pb were not statistically different. In the anatomically cured group, where mesh was inserted only in the posterior compartment, we found statistically significant changes in POP-Q points: Ap, Bp and D. Points Aa, Ba, C, TVL, gh and pb were not statistically different. In the anatomically cured group where mesh was inserted in both compartments, we found statistically significant changes in POP-Q points: Aa, Ba, C, D, Ap, Bp, TVL. Points gh and pb were not statistically different. The mesh exposure rate was 3,78%. Mean time to exposure was 12 months. De novo stress urinary incontinence (SUI) occurred in 18 (34%) patients. Mean time to SUI was 1.03 months. De novo urgency occurred in 7,55%. One year after the procedure 54% of women were not sexual active, 44% had normal sexual activity and 2% sufferred from de novo dyspareunia. There was a significant decrease in the mean VAS score from 8.52 to 3.36 in the anatomically cured group without de novo SUI, urgency, pelipathia and dyspareunia (p<. 001). The results of MRI as well as QoL questionnaires are not included in this text.
Conclusions:
The anatomically cured group in our surgically high-risk population was 83%. This number could be decreased by 3 cases (5,66%) where POP developed on the contralateral side to where the primary implant was inserted. This raised the question of whether we are able to accurately estimate the degree and extent of prolapse in all patients in the framework of clinical examination. Perhaps utilization of other imaging techniques could help (US, MRI). Nevertheless, recurrence may occur despite mesh repair. The low mesh exposure rate is associated with proper mesh placement and uterus preservation. The high incidence of de novo SUI must be included in the informed consent. Our findings suggest that the interposition of a monofilament polypropylene mesh by the vaginal route seems to be an effective procedure for repair of recurrent vaginal wall prolapse. The new methods are associated with low morbidity in the surgically high-risk population. However, some of these complications can be serious and need highly specialized management and highly skilled surgeons.

Presentation Number: 025
REATTACHMENT OF THE ENDOPELVIC FASCIA TO THE APEX DURING ANTERIOR COLPORRHAPHY. DOES THE TYPE OF SUTURE MATTER?

S. ZEBEDE, A. L. SMITH, C. K. GROSS, R. LEFEVRE, V. C. AGUILAR, G. W. DAVILA;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objectives:
To determine if using permanent suture for apical fixation during traditional anterior colporrhaphy results in improved anatomic support and decreases prolapse recurrences without an increase in healing complications.
Methods:
This was a retrospective case control study comparing patients who underwent traditional non-grafted anterior colporrhaphy including reattachment of the anterior endopelvic fascia to the apex/cervix. In all patients traditional midline plication was performed with interrupted absorbable sutures (2–0 vicryl). The final plication suture, which reattaches the endopelvic fasica to the apex was either permanent 2–0 prolene (group 1) or absorbable 2–0 vicryl (group 2) or (Fig. 1). The groups were matched in a 2:1 ratio based on age, body mass index and presenting stage of prolapse. All patients with less than 6 month available follow-up were excluded from review. The

primary outcome measure was prolapse recurrence of the anterior vaginal wall defined by POP-Q points Aa or Ba ≥ −1. Secondary outcomes include POP-Q points, suture exposures, presence of granulation tissue and any other complications. Statistical analysis included student's *t*-test, wilcoxon signed rank test, and Chi-square/Fisher exact test as appropriate.

Results:

During the study period, 230 patients underwent anterior colporrhaphy. 80 patients had reattachment of the fasica to the apex using a permanent suture and 150 an absorbable suture. No preoperative differences existed between the two groups and there were no differences in concomitant surgical procedures performed (Table 1).

TABLE 1: Patient Characteristics

	Permanent (group 1) n=80	Absorbable (group 2) n=150	*p-value*
AGE	62.8±11.6	62.9±10.6	*0.93*
BMI	26.5±4.9	26.3±5.2	*0.73*
PARITY	2 (0–5)	2 (0–12)	*0.79*
POSTMENOPAUSAL	69 (86)	123 (82)	*0.96*
SMOKER	30 (38)	62 (41)	*0.67*
PREVIOUS HYSTERECTOMY	23 (29)	41 (27)	*0.87*
PREVIOUS ANTERIOR REPAIR	4 (5)	7 (5)	*1.0*
CONCOMITIANT SURGERY			
•			
HYSTERECTOMY	36 (45)	78 (52)	*0.3*
•	16 (20)	36 (24)	*0.5*
APICAL SUSPENSION	63 (79)	112 (75)	*0.6*
•			
SUBURETHRAL SLING			

*expressed as mean ± sd, median (range), and n (%) where appropriate

Median follow-up between groups was similar at 41 weeks (24–91) in group 1 and 47 weeks (24–152) in group 2. There was improved anatomic correction as measured by anterior wall POP-Q points in the permanent suture group (Table 2). There was no difference in the primary outcome with 5 patients (6.2%) in group 1 developing prolapse recurrence and 14 (9.3%) in group 2 (p=0.46). Re-intervention rates were the same with one patient undergoing repeat surgery in group 1 and one patient in desiring a pessary in group 2. Overall patient satisfaction was high in both groups with 80% of the permanent group reporting themselves as cured and 70% of the absorbable group (p=0.2).

TABLE 2: Mean POP-Q Measurements

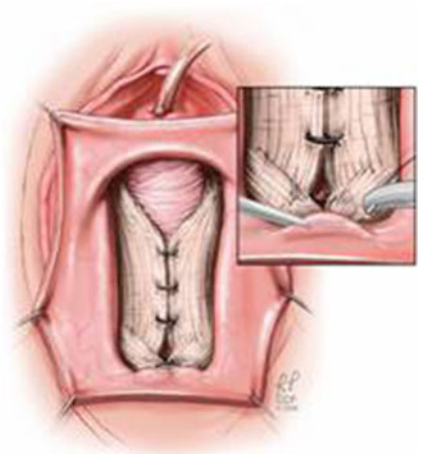
	Preoperative POP-Q			**Postoperative POP-Q**		
	Permanent (group 1) n=80	Absorable (group 2) n=150	*p-value*	Permanent (group 1) n=80	Absorable (group 2) n=150	*p-value*
Aa	0.94±1.6	0.78±1.5	*ns*	**−2.71±0.6**	**−2.53±0.7**	***0.018***
Ba	1.2±1.9	1.3±2.2	*ns*	**−2.71±0.6**	**−2.53±0.7**	***0.020***
Ap	−0.3±1.2	−0.8±1.4	*<0.01*	−2.61±1.0	−2.84±1.0	*<0.01*
Bp	−0.3±1.4	−0.5±1.7	*ns*	−2.60±1.0	−2.60±1.0	*ns*
C	−3.9±4.2	−3.3±4.2	*ns*	−8.05±1.9	−7.8±2.6	*ns*
Tvl	9.2±2.4	9.2±2.5	*ns*	8.63±2.2	8.8±1.2	*ns*
Gh	3.1±1.0	3.0±1.3	*ns*	2.13±0.8	2.10±0.8	*ns*
Pb	3.4±0.8	2.9±0.8	*<0.01*	3.75±0.7	3.75±0.6	*ns*

There was no difference in the presence of granulation tissue at 12 weeks (14% vs. 16%, $p=0.5$) between the groups. However, significantly more patients in group 1 had suture present at their 12-week examination (15% vs 2.7%, $p<0.01$) with five (6.5%) requiring in-office trimming of the exposed suture. In these patients, office trimming of the suture occurred at a median of 51 weeks after surgery. No patients in group 2 required office treatment for suture exposure.

Conclusion:

Overall, reattachment of endopelvic fasica to the apex at the time of anterior colporrhaphy results in low recurrence rates. Permanent suture used for apical fixation is associated with improved anatomical correction compared to absorbable suture, however does result in an increased rate of suture exposures and need for office treatment.

Fig. 1: Incorporation of apical tissue with proximal suture of anterior colporrhaphy



Presentation Number: 026

LONG-TERM OUTCOMES AFTER ROBOTIC VERSUS ABDOMINAL SACROCOLPOPEXY—PELVIC FLOOR SUPPORT AND FUNCTION

E. J. GELLER, B. A. PARNELL, G. C. DUNIVAN;
UNC-Chapel Hill, Chapel Hill, NC.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To compare long-term pelvic floor outcomes in women undergoing robotic versus abdominal sacrocolpopexy for advanced pelvic organ prolapse.

Background:

We conducted a retrospective study of women who underwent either robotic or abdominal sacrocolpopexy with permanent mesh from March 2006 to October 2007 at a single university hospital. Women were identified through a surgery database and divided into two groups—those who underwent robotic-assisted surgery and those who underwent abdominal surgery.

Methods:

Women were contacted and offered a visit at which time a Pelvic Organ Prolapse—Quantification (POP-Q) exam and pelvic exam were performed to assess pelvic floor support. POP-Q exam was compared between the robotic and abdominal groups, as well as within each group in comparison to the preoperative POP-Q exam. Pelvic floor function was assessed via the Pelvic Floor Distress Inventory—Short Form 20 (PFDI-20), the Pelvic Floor Impact Questionnaire—Short Form 7 (PFIQ-7) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12). Questionnaires scores were compared between the robotic and abdominal groups. The primary outcome was pelvic floor support based on POP-Q exam. Secondary outcomes included pelvic floor function as measured by questionnaire scores as well as the rate of long-term complications. Student's *t*-test, Mann Whitney U and chi-square statistics were used where appropriate.

Results:

The analysis included 64 patients (31 robotic and 33 abdominal sacrocolpopexy). Mean time since surgery at time of assessment was 44.2±6.4 months. Demographics were similar between groups, including age, race, BMI and preoperative stage of prolapse. (Table 1) More women in the robotic group underwent concurrent hysterectomy and concurrent anti-incontinence procedures; but estimated blood loss was higher in the abdominal group. In evaluating durability of pelvic support four years after sacrocolpopexy, POP -Q exam remained significantly improved in both the robotic and abdominal groups compared to baseline. The level of support at follow-up was similar between groups: Aa (−2.5 vs −2), Ap (−2 vs −2), C (−8 vs −7), TVL (8 vs 8). When assessing pelvic floor function, the robotic and abdominal routes had similar excellent function scores on the PFDI-20 and PFIQ-7 and their subscales. (Table 2) In the robotic group, 51.6% were sexually active at follow-up compared to 66.7% in the abdominal group. Both groups had relatively high sexual function based on PISQ-12 scores. There were two cases of mesh exposure in each group.

Conclusions:

Robotic sacrocolpopexy demonstrates similar long-term outcomes compared to abdominal sacrocolpopexy. POP-Q exam and pelvic floor symptom scores demonstrate lasting improvement in pelvic floor support and pelvic floor function for both groups. More than half of women continue to be sexually active, with high sexual function. Robotic sacrocolpopexy is an effective treatment alternative to abdominal sacrocolpopexy for the treatment of advanced pelvic organ prolapse.

Table 1

Demographics			

Data presented as n (%), mean ± standard deviation and median (range) for POP-Q.
* Student's *t*
†Fisher's Exact
‡ Mann Whitney U
§Pearson chi-square

Table 2

Pelvic Floor Function Based on Quality of Life Questionnaires				

Data presented as mean ± SD
All analyses performed with Student's *t* test

Presentation Number: 027

SURGICAL TREATMENT OF ANTERIOR AND/OR APICAL PROLAPSE WITH ELEVATE ANTERIOR AND APICAL®: RESULTS AT 6 MONTH AND 1 YEAR OF A PROSPECTIVE SINGLE CENTER STUDY

C. COURTIEU, A. GORON, L. PANEL;
CMC Beau Soleil, Montpellier, France.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
Assessment of safety, anatomical efficacy and functional results of Elevate Anterior and Apical® (A&A) (AMS, Minnetonka, MN, USA)

Methods:
In a prospective single center study, 95 women were operated between February 2009 and July 2010.The follow up of the patient was done at baseline, 6 weeks, 3 months(optional), 6 months and 1 year. 77/95 women completed a 6 month evaluation visit (19% missed) and 45/54 the 1 year visit (16,6% missed).. The primary evaluation endpoint at follow up was the rate of patient with Stage POP-Q≤I. Secondary endpoint was the change in symptoms (PFDI-20) and quality of life questionnaires (PFIQ-7, PISQ −12) between baseline,6 months and 1 year. Operative time, intra and immediate post operative complications, delayed complications (>6 weeks) and repeated surgery were recorded for all 77 women.
Surgical procedure was the implantation of a low wheighted polypropylene mesh by a single vaginal incision. The anterior part of the mesh is anchored in the obturator internus muscle; an apical polypropylene arm is anchored in each sacrospinous ligament. The apical end of the mesh is then secured to the arms with locking eyelets. Surgical mesh procedures were Elevate A & A alone in 57/77, associated with a posterior mesh in 20/77. Other concomitant procedures were hysterectomy in 14/77, posterior autologous surgery in 17/77 and sub-urethral sling in 4/77.
Changes between baseline, 6 months and 1 year were evaluated by a paired *t*-test or Wilcoxon signed rank test as appropriate with a level of significance at 5%.

Results:
Mean age of the patients was 66,5 years (52–83). 7/77 (9%) had recurrent prolapse.
Mean duration of surgery was 50 min (20–120) and 33 min (20–55) for Elevate A&A as single procedure (n=26)
Intra-operative complications were 2/77 bladder injuries and 1/77 bleeding of 400 cc. Postoperative complications (< 3 Mo) were 1/77 pelvic hematoma requiring transfusion but no reoperation, 4/77 transient urinary retention requiring intermittent catheterization (1–5 days), 6/77 buttock pain. Delayed complications (> 3 Mo) were 3/77 de novo posterior Stage II prolapse, 5/77 worsened or de novo stress urinary incontinence treated with sub urethral sling and 1/77 buttock pain. 1/77 (1,3%) asymptomatic vaginal extrusion occurred requiring in office triming.
At 6 months and 1 year,anatomic anterior and apical cure rate is reported in the table below

POP-Q	ANTERIOR			APICAL		
	Baseline	6 months	1 year	Baseline	6 months	1 year
Stage 0–1	0%	78%	77,8%	20,8%	92,6%	91,2%
Stage II	10,4%	20,7%	22,2%	35%	6,5%	8,8%
Stage III–IV	89,6%	1,3%	0%	44,2%	1,3% *	0%

*: 1 reoperation for elongation of the cervix

Changes in symptoms and QOL scores is reported below as mean value (SD score)

	PFDI-20	POPDI-6	UDI-6	PFIQ-7	POPIQ-7	UIQ-7	PISQ-12
Baseline (n=77)	91,1 (42,5)	40,2 (21,1)	31,5 (21,7)	71,5 (38,5)	33,2 (28,5)	26,2 (25,8)	32,4 (10,5)
6 months (n=77)	33,5* (28)	8* (12)	12,9* (13,5)	11,9* (23,2)	2,2* (9,5)	6,3* (14,9)	36,3 (6,1)
1 year (n=45)	33,2* (24,2)	6,7* (12,5)	12,5* (15,5)	13,8* (36,6)	3* (10,6)	4,8* (11,9)	35,3 (5,7)

* Statistically significant p<0,05

All the women presenting with anatomical anterior and/or apical failure showed an improvement in QOL and symptoms questionnaires. At question 3 of the PFDI-20, none of them complain of bulge in the vagina at 6 months and 1 year.
46/77 (59,7%) patients were sexually active at baseline; 6 had pre-op dyspareunia. During the follow-up, 4/46 patients stopped sexual activity, none of them related to dyspareunia., 4/46 (8,6%) of women complained of post-op dyspareunia (2 persistent pre-existing, 2 de novo 4,3%). 3 patients required infiltration for dyspareunia, with cessation of pain. 2 patients sexually inactive at baseline became active (1 dyspareunia) There was no significant change in the PISQ 12 score.

Conclusions:

The anatomical results provided with Elevate A&A are comparable to those obtained with trans obturator meshes for the anterior compartment with a relatively high rate of post-op stage II prolapse but with excellent functional results on QOL questionnaires. This type of fixation provides also very good anatomical results on apical compartment, with a single anterior vaginal approach.
We observed a very low rate of extrusion in this study related to the very low wheighted mesh and surgical options (avoidance of hysterectomy and vaginal triming, dissection below vaginal fascia) There was no adverse effect on sexual function (as the cases of de novo dyspareunia were cured by local infiltration).

Presentation Number: 028

SINGLE INCISION APPROACH FOR THE TREATMENT OF VAGINAL SUPPORT DEFECTS IN THE ANTERIOR AND APICAL COMPARTMENTS: SAFETY AND EFFICACY EVALUATION

E. J. STANFORD[1], R. D. MOORE[2], **J. W. ROOVERS**[3], J. C. LUKBAN[4], E. BATALLER[5], S. SUTHERLAND[6];
[1]Private Practice, Austin, CO, [2]Atlanta Med. Res. Inst., Atlanta, GA, [3]Academic Med. Ctr., Univ. of Amsterdam, Amsterdam, Netherlands, [4]Eastern Virginia Med. Sch., Norfolk, VA, [5]Hosp. Clínico y Provincial de Barcelona, Barcelona, Spain, [6]Metro Urology, Plymouth, MN.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:

To assess the safety and efficacy of the Elevate® Anterior and Apical (EAA) with IntePro® Lite™ (AMS, Minnetonka, MN, USA) in the repair of pelvic organ prolapse (POP).

Background:

To reduce the risks associated with trocar-based vaginal mesh implant systems, single-incision devices have been developed to eliminate the need for blind transperineal trocar passes.[1], [2]

Methods:

One hundred and forty-two women were enrolled at 16 centers (10 U. S., 6 E.U.) following an IRB or EC approved protocol. The primary outcome was treatment failure defined as ≥ Stage II POP-Q or surgical revision for recurrence anytime during follow-up. Secondary outcomes included quality of life (QOL), employing the Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire (PISQ), Pelvic Floor Impact Questionnaire, and Pelvic Floor Distress Inventory. Surgical technique for vaginal dissection and mesh implantation was standardized. Statistical analysis used paired t-tests and Wilcoxon signed-rank tests as appropriate.

Results:

Patient characteristics included a mean age of 63.9±9.8 years; BMI of 27.3±5.3; parity of 3±1; menopausal in 127 (89%); and prior hysterectomy in 62 (43.7%). One hundred and thirty-six subjects (95.8%) completed the 6 M visit Success rates for the anterior compartment and apex were 86.3% (95% CI 79.2–91.6%) and 98.8% (95% CI 93.3–100%), respectively, as shown in Table 1. All failures were stage II at 6 months. Two patients complained of bulge symptoms, yielding a subjective cure of 98.6%. Of the two, one underwent surgical revision. POP-Q measurements improved significantly (p<0.001) with a decrease in Aa from +1.2±1.3 (95% CI 1.0, 1.4) at baseline to −2.4±0.9 (−2.5, −2.2) at 6 months; Ba from 2.6±1.9 (2.3, 2.9) to −2.3±0.9 (−2.5, −2.1); and C from −0.5±3.9 (−1.2, 0.1) to −7.2±1.4 (−7.4, −6.9). TVL remained the same (8.6± 1.2, 95% CI 8.4, 8.8; p=0.927). The most common device/procedure-related adverse events were urinary tract infection (8, 5.6%), urinary retention (7, 4.9%), mesh extrusion (6, 4.2%), transient buttock pain (5, 3.5%), de novo urinary stress incontinence (4, 2.8%), hematoma (3, 2.1%), and dyspareunia (3, 2.1%). All QOL scores were significantly improved from baseline including PISQ (<0.001). Satisfaction scores revealed that 126 (94.7%) felt that they were some or a lot improved; and 124 (93.2%) were moderately, very, or extremely satisfied.

Conclusions:

Initial short-term results show that the EAA system completed through a single vaginal incision with no external needle passes is effective in treating both anterior and apical prolapse concomitantly with few complications, low mesh extrusion rates, low dyspareunia rates and high patient satisfaction. The EAA system appears to offer improvements over earlier generation mesh kits designed for anterior and apical vaginal prolapse treatment.

References:
[1] Altman D, Falconer C, for the Nordic Transvaginal Mesh Group. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. Obstet Gynecol 2007;109:303–308.

[2] Abdel-Fattah M, Ramsay I; West of Scotland Study Group. Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse. BJOG 2008 Jan;115:22–30.

Table 1

	Anterior 6 mos			Anterior 6 mos		
Baseline Stage	N Patients	N Success	%Success	N Patients	N Success	%Success
0/1	0	–	–	50	50	100
2	35	32	91.4	41	40	97.6
3/4	96	81	84.4	40	40	100
No de novo prolapse						

Presentation Number: 029

SHORT—TERM PATIENT REPORTED OUTCOME MEASURES (PROMS) FOLLOWING ELEVATE ANTERIOR INSERTION FOR ANTERIOR/APICAL COMPARTMENT PROLAPSE

N. RAUT, A. ARUNKALAIVANAN, M. BAPTISTE;
City Hosp., Birmingham, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
We aim to determine the efficacy and safety and also the PROMS following transvaginal mesh repair of anterior/apical prolapse using the Elevate anterior™.

Background:
EQ-5D (1) is a standardised measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal. This contains 5 domains (Mobility, self-care, usual activities, pain and anxiety) and a visual analogue scale (VAS). This questionnaire has been validated as a quality of life assessment for the patient reported outcome measures (PROMS) project. The PROMS includes EQ-5D and a disease-specific questionnaire -PISQ-12 (Pelvic organ prolapse/Urinary Incontinence Sexual function Questionnaire).
Because of the large dissections of transobturator passages and the use of large non absorbable meshes, transvaginal mesh repair has been thought to induce significant post-operative sexual dysfunction. A recent Cochrane review (2) revealed that the use of mesh at the time of anterior vaginal wall repair reduces the risk of recurrent anterior wall prolapse.

Methods:
The study population is women >21 years of age who have been diagnosed with symptomatic S-POP (Simplified Pelvic Organ Prolapse) (3) stage II or higher requiring surgical repair. All women underwent physical exam, before treatment (Baseline) and at 6 months after the procedure. At 6-months follow up, the impact of the procedure on PROMS as measured by EQ-5D and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) were compared with baseline.

Results:
Forty eight patients underwent the procedure. All women were followed up in the clinic at 6 months with S-POP staging. However, 28 (58.3%) women returned the EQ-5D questionnaire.

Table 1. Patients' characteristics

Variable	Value
Age	56.4±12.2
Parity	3.5±1.9
Hysterectomy	14(29.2%)
Primary procedure	29(60.4%)
For Recurrence	19(39.6%)

35(72.9%) underwent Elevate anterior alone; 7(14.5%) had concomitant posterior repair; 3 (6.3%) had both Elevate anterior and Posterior together; 3(6.3%) also underwent Midurethral tape at the same time.
10(20.8%) women were sexually active before procedure whereas 12 (25%) were sexually active after the procedure. 4 patients (8.4%) had mesh erosion needing removal; 4(8.4%) had haemorrhage ranging from 250–500 ml; 2(4.2%) developed retention of urine which improved with conservative measures. 46(95.8%) had objective improvement at stage I or less at 6 months' follow-up.
Tables 2 and 3 outline the results for the PISQ-12 and EQ-5D

Table 2. Quality of Life analysis

Variable	Before the procedure	6 months after the procedure	P value*
PISQ-12	14±7.3	13.2±5.9	0.72
VAS	54.1±24.5	71.9±21.6	<0.05

* Wilcoxon signed-ranks test

VAS- Visual Analogue Scale included in EQ-5D

Table 3. EQ-5D Assessment

EQ-5 Dimension	Problem	Before the procedure	6 months after the procedure	P value
Mobility	No	17(60.7%)	20(71.4%)	0.08
	Yes	11(39.3%)	8(28.6%)	
Self-care	No	20(71.4%)	23(82.1%)	0.18
	Yes	8(28.6%)	5 (17.9%)	
Usual activities	No	15(53.6%)	19 (67.9%)	0.04*
	Yes	13(46.4%)	9(32.1%)	
Pain	No	11 (39.3%)	19(67.9%)	0.005*
	Yes	17(60.7%)	9(32.1%)	
Anxiety	No	16 (55.6%)	21 (74.1%)	0.025*
	Yes	12 (44.4%)	7 (25.9%)	

*Statistically significant at 6 months by Wilcoxon signed-ranks test

Conclusion:
Elevate Anterior™ system is safe and effective in the management of anterior compartment prolapse repair and is associated with an overall improvement in the Quality of Life. There is no deterioration in post-operative sexual dysfunction in this study.

References:
1. Health Policy1990 Dec;16(3):199–208.
2. Cochrane Database Syst Rev. 2010 Apr 14;(4):CD004014. Review.
3. Int Urogynecol J Pelvic Floor Dysfunct. 2011 Mar;22(3):347–52. Epub 2010 Oct 9.

Presentation Number: 030

PERMANENT SUTURE USED IN UTEROSACRAL LIGAMENT SUSPENSION OFFERS BETTER ANATOMICAL SUPPORT THAN ABSORBABLE SUTURE

C. P. CHUNG, R. J. MISKIMINS, P. M. YANDELL, T. J. KUEHL, B. L. SHULL;
Scott and White Mem. Hosp., Temple, TX.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Compare outcome of uterosacral ligament suspension (USLS) procedures in relation to suture material used for apical suspension.

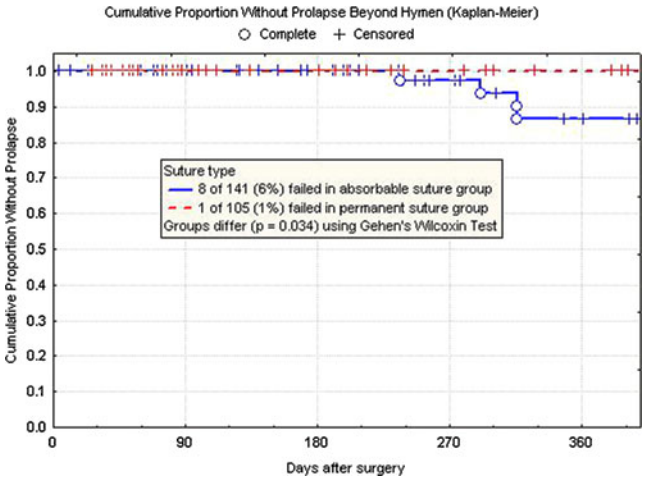
Background:
Shull et al. [1] described a transvaginal approach to repair apical and other associated sites of pelvic organ prolapse (POP) with uterosacral ligaments, and 5% had grade 2 or greater persistent or recurrent support defects. The authors describe using permanent braided suture for apical suspension. In our institution, the first suspensory suture is usually (0) absorbable polydioxanone suture which is followed by two (2–0) permanent polyester sutures on uterosacral ligaments on one or both sides of the pelvis. From 2008 to 2009, two to four absorbable (0) sutures and no permanent sutures were used on the uterosacral ligaments on one or both sides in a portion of patients. Anecdotal experience suggests that the failure rate (recurrent POP beyond vaginal hymen) was greater in those patients who had USLS with absorbable sutures as compared to those who had permanent sutures.

Method:
A retrospective design was used during a recent 2-year interval when two senior surgeons performed USLS with both suture types. Permanent (polyester) and absorbable (polydioxanone) sutures were compared for failure of apical support during follow-up exams. The permanent suture group had one absorbable and one to two permanent sutures placed on uterosacral ligaments on one or both sides while the absorbable suture group had two to four absorbable sutures placed on one or both sides of the pelvis. Failure, defined as recurrent prolapse beyond vaginal hymen, was evaluated using survival analysis with Gehen's Wilcoxin test and p-level less than 0.05 as significant.

Result:
From January, 2008 through December, 2009, 246 procedures were performed in patients averaging 62±12 (mean±SD) years of age with BMI of 27.8±5.1 kg/m^2. One of 105 (1%) patients in the permanent suture group had a loss of support to beyond the hymen while 8 of 141 (6%) patients in the absorbable suture group had loss of support. Using survival analysis the groups differed (p=0.034) in anatomic outcome during a relatively short average follow-up interval of 160 days. Duration of follow-up (average of 157 versus 162 days, respectively, p=0.86 using Student's t test) was similar between groups as was BMI (p=0.15). The patients who failed were older (70 versus 61 years, p=0.041). However, the permanent suture group patients were also older (65 versus 60, p=0.003) than those with absorbable sutures, so age was not a confounding factor in this analysis.

Conclusion:
Permanent suture use for the apical suspension component of USLS procedures offers better anatomical support.

References:
1.Shull BL, Bachofen C, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. Am J Obstet Gynecol. 2000 Dec;183(6):1365–73.



Presentation Number: 031

PELVIC ORGAN PROLAPSE AND COLLAGEN-ASSOCIATED DISORDERS

S. L. LINCE, K. LAMMERS, K. B. KLUIVERS, J. C. HENDRIKS, M. E. VIERHOUT;
Radboud Univ. Nijmegen Med. Ctr., Nijmegen, Netherlands.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
This study was undertaken to assess the association between pelvic organ prolapse (POP) and other collagen-associated diseases in women with and without POP symptoms and their relatives.

Background:
Previously, it has been reported that an alteration in collagen metabolism is relevant in the etiology of POP. Collagen is a fibrous protein and the main component of connective tissue. There are more than 20 subtypes of collagen, of which types I, III and V are the principal components that provide strength to soft tissues

Collagen-associated disorders may arise from genetic defects, that can affect any step in the normal collagen production. The most eminent inherited collagen-associated disorder is the Ehlers-Danlos syndrome (EDS). EDS patients report a higher incidence of POP, inguinal and umbilical hernia, cardiac valve prolapse, intervertebral disk displacement, rectal prolapse, varicose veins, arterial aneurysm and joint hypermobility. This suggests a common pathophysiologic pathway for both POP and the other above-mentioned disorders, in which collagen plays a central role.

Methods:
A case–control study was conducted among women presenting for gynecological care at our department and their first and second degree family members. Data were also used from women previously included in another study protocol regarding premature ovarian failure (POF), in which all female family members were elaborately interviewed. All index cases had to be over 50 years of age to be included. Index cases in the control group had to be vaginally parous as well. Index cases were assigned to the study (i.e. POP) group if they had a history of previous POP surgery or if they were ever diagnosed with POP. If not, they were included in the control group.

All participants completed a questionnaire on parity and past medical and surgical history. Besides, they answered detailed questions on the presence of the above-mentioned conditions suggestive of deficient connective tissues, regarding both themselves and their first and second-degree male and female family members.

Results:
A total of 237 women met the inclusion criteria; 165 were included during routine clinical practice and 72 were from the study on POF. Twenty-seven medical records did not include the required information. Therefore, these women were excluded from analyses. Accordingly, a total of 110 POP cases and 100 control cases were included in this study.

There were no statistical significant differences between POP and control cases regarding age (p=0.245) and BMI (p=0.268). However, control cases had a higher parity (median 3 vs 2, p= 0.014) than POP cases.

POP-cases statistically significant more often reported the presence of varicose veins (27% vs 6%, p<0.001), hypermobility (19% vs 2%, p=0.001) and rectal prolapse (25% vs 0%, p<0.001), as compared to controls. The total number of collagen-associated disorders was also higher in POP cases as compared to controls (n= 48 vs 20) This difference however, did not reach statistical significance (p=0.091).

There was no difference in the presence of collagen-associated disorders between family members of POP cases and control cases, with a total number of collagen-associated disorders of 22 vs 23 (p=0,879). However, mothers and sisters of POP cases were respectively four times (70% vs 20%) and nine times (34% vs 4%) more likely to have a history of POP compared to mothers and sisters of controls.

Conclusions:
Our study shows that POP patients are more likely to have family members with the same condition. This confirms what previous studies already reported and supports the hypothesis that a genetic predisposition to the condition exists. Since we hypothesized that this predisposition was collagen mediated, we expected more collagen-associated disorders in women with POP and their families.

Although we did not find a higher incidence of collagen-associated disorders among family members of POP cases, we did find a higher prevalence of varicose veins, joint hypermobility and rectal prolapse among POP patients as compared to

controls. The latter findings are in agreement with observations in previous reports. It seems therefore likely that a common defect, affecting collagen strength or metabolism, is responsible for these disorders.

Collagen-associated disorders in relation to POP are still poorly understood. Up till now, the connective tissues have been assessed through biochemical evaluation of the collagen metabolism in the local tissues, leading to conflicting results. Only few genetic polymorphisms have been studied so far.

Strengthened by our present findings, we speculate that the common denominator is a change in collagen strength originating from a genetic defect. Due to stretch and repair, the disorder itself may then lead to an alteration in the local collagen metabolism. More basic research into the underlying genetic cause is however needed.

Presentation Number: 032

VAGINAL PROLAPSE: IS IT A TRANSSEXUAL PROBLEM?

S. BRANDNER, A. KUHN, A. SANTI, M. BIRKHÄUSER, M. MUELLER;

Univ.sfrauenklinik Inselspital, Bern, Switzerland.

Consent obtained from patients: Yes

Level of support: Investigator initiated, no external funding

Work supported by industry: No

Objective:

A prospective non-randomized study in a tertiary referral centre of the outpatient department of gynaecology and endocrinology of the University Hospital of Bern (Switzerland). Aim of the current study was to evaluate the occurrence of pelvic organ prolapse (POP) and related bladder and bowel symptoms after sex reassignment surgery in male-to-female transsexuals.

Background:

The estimated prevalence over ten years in the former Federal Republic of Germany is 2.4:100`000 Male-to-Female transsexuals (MTF) (1). Little information is available on quality of life and factors associated with satisfaction or regret following sex reassignment surgery. Lawrence (2) found in a study of 232 male-to-female transsexuals that dissatisfaction was most strongly associated with unsatisfactory functional results of surgery. Only very few data, mainly case reports, exist referring to transsexuals after sex reassignment surgery and prolapse.

Methods:

Patients who were being treated in the regular outpatient clinic for transsexuals (TS) were asked to participate in the study. A gynaecological examination was performed in patients after sex reassignment operation and the measurements for pelvic organ prolapse applying the ICS pelvic organ prolapse staging and pelvic floor testing was done. The validated Sheffield prolapse questionnaire (SPS-Q) involving prolapse symptoms, bladder, bowel and sexual function was fullfilled by the parcipitants. Main outcome measures were ICS POP score and the Sheffield prolapse questionnaire.

Results:

52 transsexuals participated in this study. All of them were MTF. The median age was 57 years (range 39–69). Sex reassignment surgery had been 16 years previously in median (range 13–29 years) and cross-gender hormone replacement therapy had taken place ever since. Vaginal reconstruction was scrotal inversion in 49 cases and sigmoideocolpoplasty in 3 cases. Patients had been operated in 14 different centers in Switzerland, United Kingdom, France, USA and Thailand. Body mass index was 26 (Range 20–33). Table 1 shows lower urinary tract symptoms (LUTS) claimed by patients. 5.7% showed a prolapse greater or same like stage 2 and 3.8% required surgical intervention. In MTF transsexuals, one patient suffered from a total prolapse of the vagina after scrotal inversion nine years ago, and she declined conservative therapy. The symptoms were dyspareunia and a feeling of a lump. The vagina was rather short with 6 cm of length. The patient underwent laparoscopic sacrocolpopexy involving mesh insertion and surgery was uneventful. Two MTF patients demonstrated a 2^{nd} degree cystocele (point Aa 0 and 0.5 cm respectively, point Ba 0 and 0.3 cm respectively). One patient was symptomatic and underwent anterior fascial repair and the other patient was free of symptoms and it was decided to wait and see. 21% were never satisfied with their sexual function, and this was not associated with prolapse.

Conclusions:

Pelvic floor symptoms may occur in transsexuals involving bladder, bowel and sexual function even in patients without prolapse. Regarding sexual function, the current study showed a rather mixed picture of sexual function in respect to satisfaction, frequency, interference with physical activity and interference with enjoyment of life. Sexual function was not the main issue in this study, and it remains doubtful that in this group of patients prolapse is the main issue for interference with the individual sex life.

With transsexuals, we have investigated a very special group of patients with a median of nine previous operations in the past reconstructing a neovagina mainly successfully from the point of prolapse. In transsexuals, creating a new vagina per se is a great challenge and if prolapse of the neovagina occurs, few case reports describe the correction. If symptomatic prolapse occurs surgical options for the correction of prolapse should involve the individual situation as in other patients with prolapse symptoms as well. We chose sacrocolpopexy because the vagina of the patient was already shortened and we considered sacrocolpopexy as a method preventing further shortening by giving an excellent support, which it did.

References:

1. Weitze C and S Osburg Transsexualism in Germany: empirical data on epidemiology and application of the German Transsexuals' Act during its first ten years. Arch Sex Behav, 1996. 25 (4): p 409–25.

2. Lawrence AA Factors associated with satisfaction and regret following male-to-female sex reassignment surgery Arch Sex Behavior 2003; 32: 299–315

Results of the Sheffield Prolapse Questionnaire (LUTS)

General Symptom	**Never**	**Occasionally**	**Most of time**	**All of time**
Awareness of lump	48	1	2	1
Prolpase coming out of vagina	47	2	3	0
Vaginal soreness	48	2	3	0
Dragging pain in lower abdomen	44	3	3	2
Low back pain	23	12	10	4
Urinary symptoms	**Never**	**Occasionally**	**Most of time**	**All of time**
Difficulty in emptying bladder	24	17	8	0
Push prolapse to void	45	2	1	0
Urinary urgency	37	7	1	4
Urge urinary incontinence	42	1	5	1
Stress incontinence	40	3	4	3

Presentation Number: 033

EFFICACIES OF TENSION-FREE VAGINAL MESH SURGERY ON LOWER URINARY TRACT FUNCTION OVER 3-YEAR-FOLLOWUP

D. OBINATA, A. ITO, M. OKAWA, D. ASHIKARI, T. IGARASHI, T. SAKUMA, K. SATO, J. MOCHIDA, Y. OKADA, Y. YAMANAKA, K. YAMAGUCHI, S. TAKAHASHI;
Nihon Univ., Tokyo, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate anatomical and functional outcomes of the tension-free vaginal mesh (TVM) for pelvic organ prolapse (POP) over 3-year-followup.

Background:
POP is a common problem in the aging female. It has been reported that 11% of women in US have surgery for POP and/or the related condition by age 80 years. The presence of POP significantly affects the lower urinary tract function. TVM surgery has gained popularity in POP repair, and recent reports have shown that TVM surgery provided a comfortable medium/long-term cure rate. However, medium/long-term efficacies of TVM surgery on lower urinary tract symptoms (LUTS) remain unknown.

Methods:
This prospective study was performed at our single institution. This study included 210 consecutive women who underwent TVM surgery for POP from January 2005 to October 2007. Among them, we assessed 101 patients who had completed the follow-up visits for at least 3 years (mean follow-up period; 40 months). After obtaining written informed consents, anterior TVM surgery was performed in 82 individuals, posterior TVM in 1 case, and anterior/posterior TVM in 18 cases. Eighty-three cases that had clinical or occult stress urinary incontinence (SUI), which was confirmed by 1 h pad test or stress test with/without a vaginal pessary. They subsequently underwent TVM surgery concomitant with TOT urethral sling procedure. Postoperative anatomical correction of POP was evaluated by POP-Q system at every follow-up visit. Prolapse-related quality of life was assessed using Prolapse-QOL Questionnaire (P-QOL). To evaluate LUTS and the related QOL, International Prostate Symptom Score (IPSS), IPSS-QOL score, International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF), and over active bladder questionnaire (OAB-q). The IPSS, which was initially developed to assess LUTS in men with benign prostatic hyperplasia, has been recently reported to be relevant when used to examine women as well.[1]

Results:
The mean age was 66.8 years (range; 53–84). Twenty-three women were qualified as stage II in POP-Q system preoperatively, 44 and 34 cases were in stage III and IV, respectively. Postoperative anatomical cure rate (defined as stage 0) were 86% at 3 years. Seven cases were qualified as stage II at 3 years after surgery. However, all the cases experienced a significant down-stage from preoperative grade IV, and did not need further repair. All the domains of P-QOL except for Personal relationships, significantly improved during the follow-up period ($p<0.001$). Sixty-seven patients (67%) showed significant LUTS according to IPSS results, (36 and 31 cases with moderate and severe LUTS, respectively) preoperatively. Preoperative OAB-q and ICIQ-SF scores were 69 and 7.1, respectively. Postoperatively, all symptoms in IPPS significantly improved ($p<0.0001$), and were qualified as insignificant (mild) in 65% of cases at 3 years. OAB-q and ICIQ-SF also significantly improved (from 69 to 87.6; $p<0.05$ and from 7.1 to 2.6; $p<0.05$, respectively) at 3 years after surgery. As for postoperative SUI, 11% of cases who underwent TVM surgery alone, experienced de novo SUI, while only 2% of cases with TVM surgery concomitant with TOT had persistent SUI.

Conclusions:
Anatomical cure rate was 86% at 3 years after TVM surgery. TVM surgery significantly improved LUTS in women with POP, and its efficacies were maintained over 3 years. Concomitant TOT surgery prevented postoperative/de novo SUI. These findings suggest that the 3-year outcomes of TVM surgery on anatomical correction and lower urinary tract function are comfortable, and the concomitant TOT sling procedure is a reasonable option for clinical/occult SUI concurrent with POP.
References:
1. Urology 73: 1199–1202, 2009.

Presentation Number: 034

BIOMECHANICAL BEHAVIOR OF THE ANTERIOR COMPARTMENT OF HEALTHY AND PROLAPSED WOMEN BY COMPUTATIONAL SIMULATION

T. H. DA ROZA[1], T. MASCARENHAS[2], M. PARENTE[1], S. DUARTE[2], J. LOUREIRO[2], R. NATAL JORGE[1];
[1]IDMEC - Pólo FEUP, Porto, Portugal, [2]Faculdade de Med. da Univ.e do Porto - Hosp. São João, Porto, Portugal.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study is to simulate the contraction of the pelvic floor through 3D models and analyze the biomechanical behavior of the contraction in women diagnosed with prolapse with healthy women.
Background:
Pelvic organ prolapse (POP) refers to the descent of pelvic organs (including the bladder, uterus or vagina cuff and small or large bowel) into or outside of the vagina canal. This condition is frequent and negatively impacts the patient's quality of life by interfering in daily and sexual activities as well as by reducing the patient's self-esteem [1].
The anterior vaginal wall is both the most common site of POP, with 81% of surgical repairs involving the anterior wall, and also the most common site for recurrence, with failure rates as high as 40% [2]. Estimated, in the USA, cost of more than US $ 1 billion in surgical procedures for POP. Despite the high prevalence and recurrence rates this disorder, its pathophysiology is still not fully understood.
In order to better understand the biomechanics of the pelvic floor (PF), recently, three-dimensional (3D) models have been created in order to propose a better assessment and treatment in pelvic floor dysfunctions. These models allow us to simulate the contraction of the PF and propose the rehabilitation of the pelvic floor muscles with traditional method and no cost: the physiotherapy.
Methods:
We performed magnetic resonance (MR) images of 19 women (2 healthy and 17 pop). The MR images were acquired with the subject in the supine position ranging from the ischial tuberosities inferiorly, up to the upper aspect of the acetabulae. The first step to process these images is the segmentation of the pubovisceral muscle (a part of levator ani) being, after that, a geometrical model created. The next step is to generate a finite element model (FEM), where it was simulated muscle contraction up to 100% of maximum contraction (Fig. 1) [3].

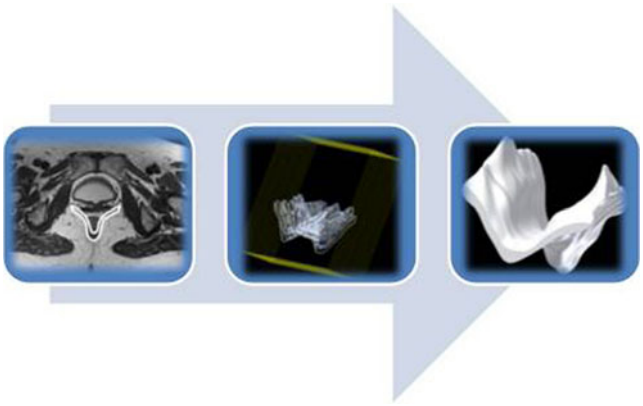
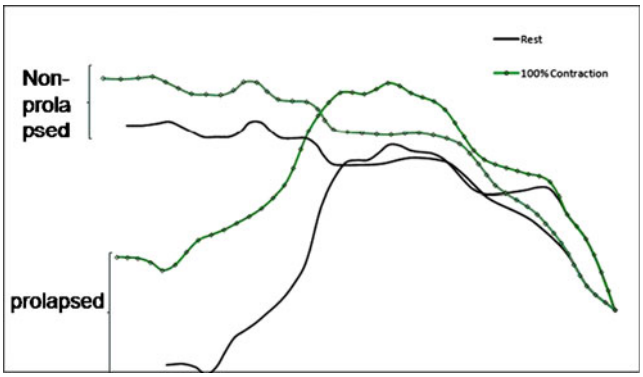


Figure 1. Constrution 3D model.

Results:
In a graph we can analyze the behavior of the PF in the sagittal plane. Note that the PF to getting healthy women can keep the contractions at higher levels compared with women with pathologies. Along with this, these contractions are maintained during the entire length of the floor, or in the three compartments.



Graph 1. PF in sagittal view. The left side represents the anterior compartment, while the right side of the posterior compartment.

In the analysis of women with dysfunction in the anterior compartment (prolapse),we may note that the muscle is not capable of performing a proper contraction at these levels, because there are functional problems. This behavior is observed in all women with prolapsed.

Conclusions:
This methodology is a technique for obtaining 3D models of anatomical structures based on MR images. These results may indicate that physical therapy (for a prolapsed woman) may not restore the integrity of PF muscles function.
References:
[1] Am J Obstet Gynecol. 2005.
[2] Clin Obstet Gynecol. 2005.
[3] Int Urogynecol J Pelvic Floor Dysfunct. 2008.

Presentation Number: 035

AVULSION OF PUBORECTALIS MUSCLE. IS IT A MYTH?

A. DERPAPAS, M. S. HAMADY, P. GALLO, G. A. DIGESU, G. VIJAYA, C. DELL'UTRI, R. FERNANDO, V. KHULLAR; Imperial Coll. Hlth.care NHS Trust, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To evaluate the prevalence of puborectalis muscle avulsion in women with and without pelvic floor dysfunction (PFD) using computed tomography (CT).

Background:

Birth-related levator ani (LA) muscle injury is considered to play a key role in the pathogenesis of pelvic organ prolapse (POP), however it does not account for all POP.[1] The link between childbirth and stress urinary incontinence (SUI) is less consistent. Recent 3D/4D translabial ultrasound studies have reported 18-35% prevalence of puborectalis muscle avulsion in parous women with symptoms of PFD.[2] Studies with magnetic resonance imaging (MRI) have demonstrated that different types of LA injury exist in up to 20% of parous women. It has been suggested that such injuries may arise partially due to detachment of the puborectalis from its origin and partially due to denervation while the muscle connection to the posterior surface of the pubic bone remains intact.[3] Moreover, morphometric characteristics of the LA such as muscle thickness and volume have shown great variability in imaging studies due to age- and hormonal status-related muscle atrophy. Spiral CT scanning of the pelvis provides detailed anatomical images with very reliable distinction between muscle, fat and bone and without motion and chemical shift artefacts seen in MRI.

Methods:

Women with or without symptoms of PFD were studied in a tertiary referral urogynaecology centre. Women were recruited from the Department of Radiology, where they were referred for a pelvic CT scan due to various pathologies. Assessment included a detailed clinical interview and completion of King's Health and Prolapse-Quality of Life questionnaires. Maternity on-line records were searched to cross-match details of obstetric history. All women underwent spiral CT scan of the pelvis from the level of the iliac crest to 3 cm below the level of the symphysis pubis. The data set was reconstructed using 1 mm slice thickness without any gaps. Measurements of the puborectalis muscle maximum thickness were taken at the para-axial level defined by the line connecting the inferior most border of the symphysis pubis and the anorectal angle. Bilateral attachments of puborectalis muscle to the pubic rami were identified and measurement of the levator symphysis gap (LSG) was taken in cases with puborectalis complete detachment. Statistical analysis by using Mann Whitney-U test and bivariate analysis between the morphometric and obstetric variables was performed ($P<0.05$).

Results:

One hundred and thirteen women were recruited in total. Three women were excluded from further analysis due to poor image quality. Mean age was 61 (18–90) and median parity was 2 (0–10). Twenty-five per cent of women were nulliparous, whereas 68% of parous women had more than two deliveries. Ninety-two per cent of women had vaginal deliveries only and 8% had delivered either by caesarean section only or had experienced both modes of delivery. 86% of women reported prolapse and urinary incontinence symptoms, with 6% having undergone previous prolapse repair or/and continence procedure. Unilateral or bilateral detachment of the puborectalis muscle from the pubic rami was evident in only in 5 cases (4.5%), with the LSG ranging from 17.30 to 25.40 mm. No detachments were noted in nulliparous women. In cases with intact muscle bilaterally, the median distance of the right and left muscle attachment to the symphysis pubis was 21.2 mm (12.90–30.70) and 22.5 mm (11.5–29.2) respectively. The maximum thickness of the left puborectalis was significantly smaller in nulliparous than in parous women (mean difference 4.9±1.2 mm, $p=0.04$). The puborectalis attachment was also markedly thinner on the left side in women with duration of second stage of labour >2 h, however this difference did not reach statistical significance ($p=0.06$). There was no statistically significant correlation between avulsion and symptoms of PFD.

Conclusions:

Our cross-sectional study on the LA morphology in symptomatic and asymptomatic women with spiral CT imaging demonstrated a 4.5% prevalence of puborectalis avulsion. Avulsion was not associated with pelvic floor dysfunction symptoms. A thinner left puborectalis muscle bulk with increased parity may be attributed to atrophic changes as a result of childbirth injury and could perhaps account for the high prevalence of avulsion previously reported in lower spatial resolution imaging techniques such as 3D/4D ultrasound.

1. Obstet Gynecol. 2007 Feb;109(2 Pt 1):295–302.
2. Obstet Gynecol. 2005 Oct;106(4):707–12.
3. Obstet Gynecol 2003;101:46–53.

Presentation Number: 036

THE INTRA AND INTER-OBSERVER RELIABILITY OF THE THREE-DIMENSIONAL ULTRASOUND IMAGING OF FEMALE URETHRAL SPHINCTER

A. DIGESU, A. DERPAPAS, P. GALLO, C. DELL'UTRI, G. VIJAYA, C. HENDRICKEN, R. FERNANDO, V. KHULLAR; Imperial Coll. Sch. of Med., London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To assess the intra and inter-observer reliability of the 3D ultrasound imaging in the measurement of the urethral sphincter.

Background:

Urethral sphincter is believed to play an important role in the pathogenesis of lower urinary tract symptoms (LUTS). It has been assessed in the past using 2D ultrasound imaging and different mathematical formulas have been suggested to measure its volume. However, the urethral sphincter is neither a sphere nor

an ellipse and in view of its atypical geometric shape, formulas should not be used. In the last decade, 3D ultrasound imaging has been introduced in urogynaecology as a novel technique to evaluate urethral sphincter volume in both pregnant and incontinent women. It has also been shown to be a promising preoperative tool in evaluating the outcome of continence surgery. However, the reliability of 3D ultrasound imaging in the assessment of the urethral sphincter has been poorly studied to date.

Methods:

Women undergoing transvaginal ultrasound scan for benign gynaecological conditions were recruited. Only those who agreed to participate and did not suffer from any LUTS were studied. A 3D translabial ultrasound scan of the urethra was performed with women lying supine with their legs abducted and an empty bladder. A GE Voluson-i system with 4–8 MHz curved array 3D/4D ultrasound transducer was used. If the urethral sphincter was not visualized adequately in its entirety with the surrounding tissue, the scan was repeated. When a clear image of the urethra and rabdosphincter was obtained in B-mode, a volume box was placed around the urethra, bladder neck and surrounding tissues and 3D images were then taken using a slow scan time. The volume box used was 8 cm size in order to have parallel section increments of <0.5 mm. Using this technique, the probe scanned automatically through an arc of 110º taking 250 images allowing a simultaneous visualization of sagittal, transverse and coronal sections. These images were then computer regenerated into a 3D picture. In the sagittal plane the measurements recorded included the distance from the bladder neck to the proximal rhabdosphincter, the bladder neck to the maximal cross-sectional area of the rhabdosphincter and the maximal rhabdosphincter length. The cross-sectional area of the total sphincter was serially traced recording each area from one end to the other using 1 mm thickness' slices to calculate the area. When the entire sphincter was traced, a volume was computed automatically. The process was repeated for the inner core of the sphincter. Finally the volume of the inner core was subtracted from the total volume to give a measurement of the rhabdosphincter volume. All measurements were taken twice by the same clinician 2 weeks apart to assess the intra-observer reliability. A second blinded experienced clinician re-measured all parameters to assess the inter-observer reliability. The Interclass correlation coefficient (ICC) was calculated to assess limits of agreement. Altman's classification of the reliability values was used. ICC values under 0.20 were considered poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good and 0.81–1.00 very good. Local Ethical approval was obtained.

Results:

37 asymptomatic nulliparous women were studied. The whole scanning time was 4–6 s. Table 1 shows the urethral sphincter parameters of the study population. Table 2 shows ICC and limits of agreement of measurements taken 2 weeks apart by the same clinician. Table 3 shows ICC and limits of agreement between the 2 investigators.

Table 1.

Parameter	Mean (±SD)	5th centile	95th centile
Total sphincter volume (cm^3)	5.7 (1.4)	3.6	8.8
Internal sphincter volume (cm^3)	0.4 (0.2)	0.2	0.9
Rabdosphincter volume (cm^3)	5.3 (1.4)	3.4	8.5
Maximal urethral length (cm)	3.8 (4.6)	2.3	6.6
Maximal rhabdosphincter length (cm)	1.7 (0.25)	1.4	2.3
Distance from bladder neck to proximal rhabdosphincter (cm)	0.7 (0.2)	0.4	1.1
Distance from bladder neck to maximal cross-sectional area(cm)	1.7 (0.9)	0.9	2.5

Table 2.

Parameter	Mean of difference	95% Limits of agreement		ICC
		Lower	Upper	
Total sphincter volume (cm^3)	0.154	0.898	0.973	0.948
Internal sphincter volume (cm^3)	0.007	0.987	0.997	0.993
Rabdosphincter volume (cm^3)	0.208	0.863	0.972	0.945
Maximal urethral length (cm)	−0.801	−0.863	0.506	0.641
Maximal rhabdosphincter length	0.040	0.864	0.964	0.930
Distance from bladder neck to proximal rhabdosphincter (cm)	0.020	0.982	0.995	0.991
Distance from bladder neck to maximal cross-sectional area (cm)	−0.027	0.758	0.936	0.875

Table 3.

Parameter	Mean of difference	95% Limits of agreement		ICC
		Lower	Upper	
Total sphincter volume (cm^3)	0.220	0.561	0.884	0.976
Internal sphincter volume (cm^3)	0.438	0.987	0.997	0.774
Rabdosphincter volume (cm^3)	0.218	0.934	0.983	0.896
Maximal urethral length (cm)	−0.052	−0.105	0.625	0.973
Maximal rhabdosphincter length	0.590	0.315	0.818	0.747
Distance from bladder neck to proximal rhabdosphincter (cm)	−0.078	−0.667	0.958	0.942
Distance from bladder neck to maximal cross-sectional area (cm)	−0.208	−0.462	0.891	0.887

Conclusions:
3D ultrasound imaging using multiple axial cross-sectional areas at set distances is a reliable and accurate tool in the evaluation of the urethral sphincter. The described technique should be used instead of mathematical formulas as the urethral sphincter is not a uniform geometrical sphere. This is the first study showing normative values in asymptomatic non-pregnant women thus being of clinical help in the assessment and counselling of women with LUTS.

Presentation Number: 037
ASSOCIATION OF LEVATOR ANI DEFECTS AND BONY PELVIS DIMENSTIONS
M. B. BERGER, S. K. DOUMOUCHTSIS, J. O. DELANCEY; Univ. of Michigan, Ann Arbor, MI.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To investigate relationships between levator ani (LA) defects and bony pelvis dimensions.
Background:
LA defects are found at higher prevalence in women with pelvic floor disorders [1]. Differences in bony pelvis dimensions are also associated with pelvic floor dysfunction [2]. However, it is unknown if LA defects are associated with differences in bony pelvis dimensions.
Methods:
This is a secondary analysis of a case–control study of women with pelvic organ prolapse (POP) and women with normal pelvic support. All subjects underwent POP quantification (POP-Q) and pelvic magnetic resonance imaging (MRI). Prolapse was defined as the most distal POP-Q point ≥1 cm below the hymen and normal support as all points ≥1 cm above the hymen.
Inclusion criteria include MRI available with relevant landmarks visible, and either no LA defects or the presence of severe bilateral defects (LA defect score 5 or 6 [3]). The interspinous diameter, intertuberous diameter, pubic angle and sacrococcygeal-infrapubic point (SCIPP) length were measured from MRI independently by 2 authors using ImageJ software. The average value of each measurement was used for final calculations. Statistical analyses were Student's *t*-test or Mann–Whitney U test for continuous variables and chi-squared tests for proportions.
Results:
The study groups (women with no LA defects versus those with severe bilateral defects) consisted of 112 and 50 women, respectively, and are well matched by age, height, body mass index (BMI) and parity. As expected, the prevalence of POP is higher in the group with severe bilateral LA defects (Table 1).
The only statistically significant difference in bony pelvis dimensions between the groups is SCIPP length, which is 2.5% shorter in women with severe bilateral LA defects than in women with no defects (Table 2).
The subjects were next stratified into subgroups of POP or normal support to control for possible confounding of POP. Within the POP subgroup, subjects were overall well matched except the women with no LA defects had higher BMI and apical support (Table 3). The only statistically significant difference again is the SCIPP length, measuring 4% shorter in women with severe bilateral LA defects than in women with no defects (Table 3). Analysis could not be performed for women with normal support as only one subject in this subgroup had severe bilateral LA defects.
Severe bilateral LA defects were predicted by logistic regression using demographics, POP-Q and bony pelvis dimensions as independent variables. The final model, utilizing only variables significant in bivariate analyses, includes the maximum dependent point from POP-Q (a proxy of prolapse size) - odds ratio (OR) 1.76, $p<0.001$, and the SCIPP length—OR 0.95, p 0.03.
Conclusions:
The bony pelvis is similar in women with severe bilateral LA defects and in those with no defects. However, the SCIPP is shorter in women with severe LA defects. The presence of severe bilateral LA defects is associated with prolapse size and SCIPP length.
The relationship between SCIPP length and LA defects may reflect anatomic changes resulting from LA avulsion and/or risk factors for LA trauma. For example, bilateral LA defects might lead to a widened anterior-posterior (A-P) pelvis dimension due to loss of muscle tone. By contrast, a narrow pelvis may predispose to severe LA stretch during birth, or need for forceps-assisted

delivery, either of which could increase the prevalence of severe bilateral LA defects. Our study design does not allow determination of causality, but our findings support the birth-related hypotheses, i.e., there may be a threshold A-P pelvic dimension, or SCIPP length, below which the risk for traumatic birth injury is increased.

All data presented as Mean ± SD, Median (interquartile range) or Percentage (number/total)

Table 1 - Subject Characteristics

	No LA Defects (*N*=112)	Severe bilateral LA Defects (*N*=50)	p value
Age (y)	55.1±11.7	55.4±12.5	0.90
BMI (kg/m^2)	26.9±4.9	25.8±5.0	0.20
Height (in)	64.1±2.6	64.4±3.3	0.46
Vaginal Parity	2.4±1.8	2.5±1.4	0.63
Ba (cm)	−1.0 (−2.0, −1.0)	2.0 (0.0, 3.0)	**<0.001**
C (cm)	−6.0 (−7.0, −5.0)	−1.0 (−3.9, 3.0)	**<0.001**
Bp (cm)	−2.0 (−2.0, −1.0)	0.0 (−2.0, 1.0)	**<0.001**
Prolapse (%)	29.5% (33/112)	98% (49/50)	**<0.001**

Table 2 -Bony Pelvis Dimensions & LA Defects

	No LA Defects (N=112)	Severe Bilateral LA Defects (*N*=50)	p value
Interspinous Diameter (cm)	10.6±0.8	10.6±0.7	0.997
Intertuberous Diameter (cm)	11.2±1.0	11.1±0.8	0.68
Pubic Angle (deg)	89.2±7.3	88.2±7.2	0.45
SCIPP (cm)	11.9±1.0	11.6±0.7	**0.04**

Table 3 - Women with POP

	No LA Defects (*N*=33)	Severe Bilateral LA Defects (*N*=49)	p value
Age (y)	54.0±13.3	55.3±12.6	0.67
BMI (kg/m^2)	28.3±5.9	25.8±5.0	**0.05**
Height (in)	3.1±2.2	2.5±1.4	0.19
Vaginal Parity	63.8±2.7	64.4±3.3	0.32
Ba (cm)	1.0 (−1.0, 2.5)	2.0 (0.0, 3.0)	0.16
C (cm)	−4.3 (−5.4, −1.3)	−1.0 (−3.5, 3.0)	**0.01**
Bp (cm)	1.0 (−1.8, 1.0)	0.0 (−2.0, 1.0)	0.41
Interspinous Diameter (cm)	10.7±0.9	10.6±0.7	0.54
Intertuberous Diameter (cm)	11.4±1.1	11.1±0.8	0.16
Pubic Angle (deg)	90.2±8.1	88.2±7.3	0.24
SCIPP (cm)	12.1±0.8	11.6±0.7	**0.007**

References:
[1] *AJOG* (2010) **202**:488.e1–6
[2] *Obstet Gynecol* (2003) **102**:1283–90
[3] *Int Urogynecol J* (2007) **18**:773–8

Presentation Number: 038

THE IMPACT OF ROUTINE PREOPERATIVE OFFICE CYSTOURETHROSCOPY ON THE SURGICAL MANAGEMENT OF URINARY INCONTINENCE AND PELVIC RECONSTRUCTION

B. L. TOZER, A. P. WOODWARD, A. M. TRAN, E. J. GILL; VCUHS, Richmond, VA.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to determine the rate at which preoperative cystourethroscopy altered the management of women undergoing surgical treatment of urinary incontinence and pelvic floor reconstruction.

Background:
Previous investigators have demonstrated that preoperative cystourethroscopy adds important clinical information by providing an anatomic assessment of the lower urinary tract and contributing to the diagnosis of conditions that are more difficult to recognize by physical exam and urodynamic testing, such as intrinsic sphincter deficiency and urethral diverticula (1). Other benefits include the recognition of a potential malignancy or other anatomic abnormality, such as a nonfunctioning ureter, that may alter surgical management. Taking into consideration the time, expense, and discomfort to the patient, the question remains whether or not routine preoperative office cystourethroscopy is a valuable assessment modality for all patients undergoing pelvic floor reconstruction and surgical correction of urinary incontinence with intraoperative cystoscopy so readily available and often performed routinely.

Methods:
This was a retrospective chart review including all women undergoing surgery for the management of urinary incontinence and pelvic reconstruction at a single academic urban tertiary care center between January 2004 to December 2009. Demographic data including age, race, and BMI were obtained. All preoperative cystoscopy reports were reviewed and abnormal findings that altered surgical management were recorded. Patients with other indications for a preoperative cystourethroscopic evaluation, such as hematuria, suspected urethral diverticulum, recurrent urinary tract infection, or those with prior pelvic reconstructive surgery were excluded from the study.

Results:
A total of 283 women underwent preoperative office cystourethroscopy prior to surgical management of urinary incontinence and pelvic floor defects during the study period with 235 of those meeting the study inclusion criteria. Of the total included in the study, 72 had an anti-incontinence procedure alone, 27 had a pelvic reconstructive procedure alone, and 136 had both a pelvic reconstructive procedure with a concomitant anti-incontinence procedure. Of the 235 patients, 5 (2%) had abnormal preoperative cystourethroscopic findings, including new diagnoses of bladder calculus (2), absent ureteral outflow (2), and suspicious bladder lesion (2), with one patient accounting for two of the abnormal findings. Of the two women with absent ureteral outflow, both had subsequent evaluation with normal functioning ureters and thus their surgical management was unchanged. The two women with suspicious bladder lesions were both diagnosed with transitional cell carcinoma. One underwent a cystoscopic excision at the time of her anti-incontinence procedure and the other was managed separately by a urologist with subsequent surgical treatment of her incontinence. All women in this study ultimately underwent the original planned incontinence and/or pelvic reconstructive surgery. However, two of the unanticipated diagnoses altered the surgical planning of those women (<1% of all patients).

Conclusions:
In conclusion, performing cystoscopy preoperatively in all women with symptoms of urinary incontinence and pelvic organ prolapse may be an unnecessary and redundant step. This retrospective chart review identified less than 1% of women in whom this procedure changed the preoperative management.

References:
1. *Int Urogynecol J* 1996; 7:307–311

Presentation Number: 039

DETERMINATION OF RESIDUAL URINE VOLUME BY TRANSLABIAL ULTRASOUND

D. VELEZ[1], K. L. SHEK[2], A. MARTIN[3], H. DIETZ[4];
[1]UNIVERSIDAD NACIONAL AUTONOMA DE MEXICO, Distrito Federal, Mexico, [2]Sydney Med. Sch. Nepean, Sydney, Australia, [3]Sydney Med. Sch. Nepean, Penrith, Australia, Sydney, Australia, [4]Sydney Med. Sch. Nepean, Penrith, Australia, Sydney, Mexico.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
This study was designed to determine a formula for estimation of residual urine volumes by translabial ultrasound (US).

Background:
Translabial US is increasingly used in the assessment of women with pelvic floor dysfunction. Commonly, such a work-up includes estimation of postvoid residual urine volume (PVR) which can be determined by catheterisation, transabdominal or transvaginal US [1]. It is convenient to measure PVR at the time of a pelvic floor US, since this is usually done after bladder emptying, in order to maximise pelvic organ descent [2]. To date, we have used a formula designed for transvaginal US (Volume in ml=5.9 (Height x Depth) - 14.6) [1]. This

formula has the disadvantage of producing negative results at low linear measurements.

Methods:

Data were collected from patients seen at a tertiary urodynamic centre for an interview, multichannel urodynamic testing, pelvic floor US using 4D systems [3] and a clinical examination using the ICS POP-Q system. Measurements of Height (H) and Depth (D) were taken from a midsagittal image of the bladder (see Fig. 1) obtained by translabial US, blinded against the urine volume obtained by catheterisation immediately thereafter. The relationship between PVR and the product of the Height and Depth translabial US measurements was modelled using linear regression with the intercept set to 0. The predictive performance of the resultant regression equation was quantified using Pearson's correlation and the associated R^2 statistic. Ethics approval had been obtained from the local Human Research Ethics Committee (reference 2010/50).

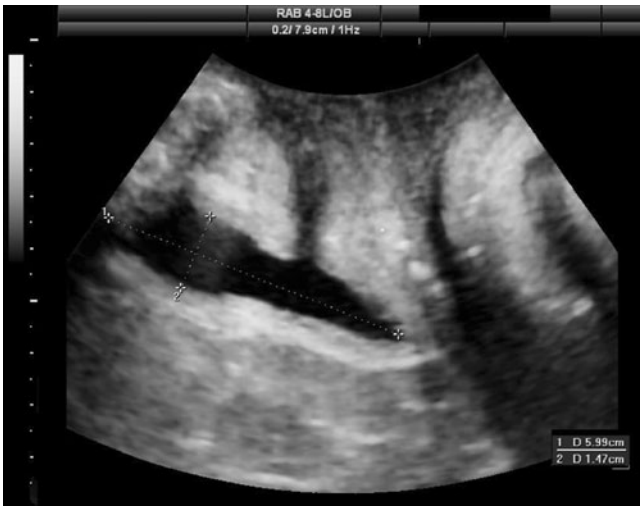


*Figure 1: Determination of residual urine volume by translabial US. Measurements obtained along the two longest axes are 5.99 * 1.47 cm. The original formula [1] yields a volume of 37 ml, the new formula 49 ml.*

Results:

214 patients were seen for urodynamic testing between July 2009 and November 2010. Average age was 55.5 (range 18–86) years. The mean BMI was 29.7 (17.3-56.6). A vaginal delivery was reported by 191 (89%), mean vaginal parity was 2.7 (0–10). A previous hysterectomy was reported by 58 (27%) and previous anti-incontinence procedures by 41 (19%). Patients reported symptoms of stress incontinence (n=170, 79%), urgency incontinence (n=172, 80%), nocturia (n=105, 49%), of voiding dysfunction (n=55, 26%), frequency (n=74, 35%), and of prolapse (n=95, 44%). Urodynamic stress incontinence was documented in 151 patients (71%), detrusor overactivity in 67 (31%). 243 postvoid residuals were obtained by catheterisation using a single use 12 French female in-out catheter in 207 individuals (range, 0–650 ml, IQR 0–105). Data from 7 patients was unavailable due to clerical failure. On testing the original formula, results correlated well with catheterised volumes (Pearson's correlation 0.96 and r^2 0.92). However, lower volumes are systematically underestimated. A new regression model comprised the product of the Height and Depth ultrasound measurements as sole covariate (i.e. HxD) and a coefficient of 5.59 (SE=0.088, 95% CI: 5.41 to 5.76, $p<0.0001$). A mixed linear model was fitted to adjust for possible non-independence between two repeated measurements obtained from 36 patients and gave virtually identical results to the linear regression model. The regression equation, (HxD) x 5.59, accounted for 94% of the variation in PVR results (i.e. an R^2=0.94 and a Pearson's correlation of 0.97).

Conclusions:

Translabial US is a convenient and highly accurate method for measuring PVR in the context of an imaging assessment of the pelvic floor. It is noninvasive, allows simultaneous evaluation of the pelvic floor and organ descent on Valsalva, and it can be performed with 3.5–6 MHz curved array transducers that are commonly used for imaging of the abdomen and/or the fetus. We propose the formula "Height*-Depth*5.6 = residual volume in ml" to estimate residual urine volume on translabial US.

References:

1. Br J Urol 1989; 63: 149–151
2. Int Urogynecol J 1999,10:3–6.
3. Am J Obstet Gynecol 2010; 321–334

Presentation Number: 040

INCIDENCE OF URINARY INFECTION IN WOMEN AFTER URODYNAMIC STUDY (UDS)

E. Y. HIRAKAUVA, R. A. CASTRO, E. M. ZUCCHI, C. RODRIGUES, P. C. FELDNER, M. G. SARTORI, M. J. GIRÃO, Z. I. JÁRMY-DI BELLA;
Federal Univ. of São Paulo, São Paulo, Brazil.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The objective of this study is to evaluate the efficacy of antibiotic prophylaxis before UDS.

Background:

UDS involving catheterization of the lower urinary tract. The prevalence of urinary tract infection after UDS ranges from 1% to 30%.

Studies of prophylactic antibiotics for UDSs have offered data of contradictory and limited predictive values. Some investigators

concluded that prophylactic antibiotics were valuable and others have not.

Material and Methods:

Women affected by lower urinary tract dysfunction undergoing conventional UDS were eligible for this study. All patients had presented normal results previous to the study for uroculture. They were randomized in four groups: group A received placebo, group B received 500 mg of levofloxacin, group C received 80 mg trimethoprim and 400 mg sulfamethoxazole and group D received 100 mg of nitrofurantoin.

The exclusion criteria were alergy to the antibiotics, pregnancy, diabetes mellitus, intermitent self-catheterization, use of permanent urinary catheter, previous antibiotic use, evidence of urinary tract infection, genital prolapse stadium III and IV and kidney stones.

After 15 days of UDSs the uroculture were repeated on all groups.

Results:

From 2008 to 2010, 141 patients were included; 43 of group A and 6 of them (13,9%) presented uroculture positive, 46 of group B and 1 of them (2,17%) presented uroculture positive. 30 of group C and 22 of group D, both with uroculture negative.

Table 1: Incidence of urinary infection between the groups

	Group A	Group B	Group C	Group D
Total	43	46	30	22
Uroculture positive	6 (13,9%)	1 (2,17%)	0 (0%)	0 (0%)
Uroculture negative	37 (86,1%)	45 (97,83%)	30 (100%)	22 (100%)

There is statistical difference between the groups. The incidence of urinary infection was significantly higher in the placebo group compared with the other groups (chisquare: 10,84; p=0,013—Fisher test: p=0,02).

Conclusion:

This study compared placebo group and 3 different antibiotics to prevent UTI. The placebo group presented significantly higher infection than the others 3 groups. No difference was founded between the antibiotics. The conclusion is the antibiotic prophilaxys is necessary to prevent urinary infection in women before performing UDS.

Presentation Number: 041

ATMOSPHERIC TEMPERATURE VARIATION IS NOT ASSOCIATED WITH BLADDER DIARY OR URODYNAMIC PARAMETERS

S. SWAMY, R. CARTWRIGHT, V. KHULLAR;
Imperial Coll. London, LONDON, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To assess the association between atmospheric temperature, bladder diary variables, symptom severity, and urodynamic parameters in women with lower urinary tract symptoms.

Background:

Bladder cold receptors have excitatory effects on the detrusor muscle [1]. At a population level there are small seasonal effects on the prevalence of clinically relevant lower urinary tract storage symptoms [2], and a significant interaction with overactive bladder treatment response [3]. However, the effect of outdoor temperature variation on clinical assessment of lower urinary tract symptoms has not been explored.

Methods:

Consecutive women referred for urodynamic evaluation at one centre were asked to complete both a 3 day bladder diary, and standardised lower urinary tract symptom questionnaire, before undergoing multichannel saline cystometry. Local mean monthly temperatures were extracted from national meteorological records. Multivariate logistic regression models adjusting for age, were constructed to test for the effect of mean temperature on recording of daytime frequency ≥8, nocturia ≥2, urinary urgency, urgency urinary incontinence, stress urinary incontinence, and urodynamic diagnosis of detrusor overactivity. Pearson's correlation was used to test for an association of quantitative urodynamic variables with temperature. Analyses were conducted using SPSS v19.0.

Results:

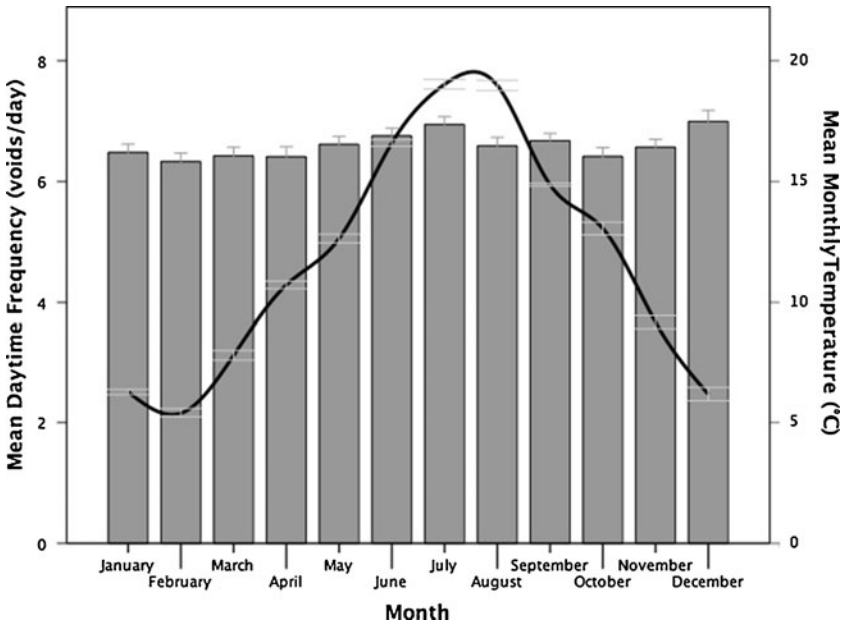
2393 women attending for urodynamics over a period of 4 years completed bladder diaries. Over the period of study, the coldest month was February, with a mean temperature of 5.4°C, while August was the warmest month with a mean temperature of 18.8°C. There were no significant differences in mean daytime frequency or nocturia by season. There was no effect of mean temperature on the reported frequency≥8 (p=.12), nocturia≥2 (p=.54), urinary urgency (p=.83), urgency incontinence (p=.80), stress incontinence (p=.27), or on the diagnosis of detrusor overactivity (p=.98). After Bonferroni correction, correlation of mean temperatures with cystometry and uroflowmetry parameters, including volumes of first sensation, maximum cystometric capacity, peak flow rate, and maximum voiding pressure, did not reveal any significant associations.

Conclusions:

Atmospheric temperature variation does not have a clinically relevant effect on any of the conventional tools used in the assessment of women with lower urinary tract symptoms.

References:

1. Br J Urol 1991;67(3):275–9
2. J Urol 2007;69(5):864–70
3. Neurourol Urodyn 2006;25(6):612–3



Presentation Number: 042

URODYNAMIC VOIDING PARAMETERS: DO DIFFERENCES EXIST BETWEEN STRESS INCONTINENCE AND INTRINSIC SPHINCTER DEFICIENCY?

C. K. GROSS, A. L. SMITH, D. R. KARP, V. C. AGUILAR, G. W. DAVILA;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
This study was conducted to determine if patients with intrinsic sphincter deficiency (ISD) have different voiding patterns when compared to those with stress urinary incontinence (SUI).

Background:
ISD refers to a subset of patients with SUI whose incontinence is caused by the inability of the urethral sphincter mechanism to remain closed either at rest or with movement. [1] Studies have shown that voiding parameters in incontinent women are different when compared to healthy cohorts likely due to the lower urethral resistance.[2] We compared voiding parameters in ISD and SUI patients to determine if differences exist between the two.

Methods:
This was a retrospective cohort study, performed between January 2008 and December 2010 at a single institution, in which voiding and urethral function urodynamic parameters were analyzed. All patients who underwent multichannel urodynamic studies with an urodynamic diagnosis of SUI with or without ISD were included. A diagnosis of ISD was made by maximal urethral closure pressure ≤20 cm H_20 and/or Valsalva leak point pressure ≤60 cm H_20. Patients were then divided into two groups according to their diagnosis of ISD (group 1) or SUI (group 2).

Urodynamic testing was performed in a standardized fashion using air charged catheters. Valsalva leak point pressure measurements were performed at 150 ml and maximum cystometric capacity. Maximal urethral closure pressures were determined with an automatic puller at cystometric capacity. Pressure flow study was performed in a sitting position.

Statistical analysis was performed using JMP_R 8.0. Comparisons were made using the Wilcoxon signed-rank test and chi-square/fisher exact test where appropriate. A value of $p<0.05$ was considered statistically significant.

Results:
During the study period, 325 patients were identified with urodynamic stress incontinence and interpretable pressure flow studies available for review. Of these patients, 203 had ISD and 122 SUI. Patients with ISD were significantly older than those with SUI (70.5±12 vs. 57.0±12 years, $p<0.01$). The ISD group had significantly more detrusor instability compared with the SUI group [70 (35%) vs. 22 (18%), $p<0.01$)].

There were no significant differences between the groups in first sensation, bladder capacity, Valsalva voiding patterns, flow time, and post-void residual (Table 1). During pressure flow studies, patients with ISD had significantly lower peak and mean flow rates compared with the SUI group (Table 1). In addition, the ISD group had significantly lower detrusor voiding pressures (P det @ qmax) compared with the SUI group (13.3±11 vs. 18.2±11 cm H_20, $p<0.01$). (Table 1).

*TABLE 1: Urodynamic parameters**

	ISD n=203	SUI n=122	*p-value*
1st sensation (mL)	71.2±51	64.6±48	*0.2*
Delayed 1st sensation (>100 mL)	48 (24)	19 (16)	*0.09*
Capacity (mL)	383.5±118	391±109	*0.5*
Increased capacity (>600 mL)	19 (9)	8 (7)	*0.4*

Overactive detrusor	70 (35)	22 (18)	***0.002***
Neurogenic bladder	8 (4)	2 (2)	*0.3*
VOIDING PARAMETERS			
Voided volume (mL)	312.1±141	348.3±141	***0.03***
PVR (mL)	51.9±61	35.9±39	***0.008***
Elevated PVR (>100 mL)	39 (19)	14 (11)	*0.08*
Flow time (s)	59.0±35	63.5±79	*0.7*
Qmax (mL/s)	15.3±9	16.8±8	***0.02***
Qave (mL/s)	6.3±3	7.4±4	***0.01***
p detrusor (Qmax) (cm H_20)	13.3±11	18.2±11	***<0.0001***
Abnormal void	83 (41)	50 (41)	*1.0*

*expressed as mean ± sd and n (%) where appropriate

Conclusions:
Significant differences exist in voiding parameters when stress incontinent patients with ISD are compared to those without ISD. Patients with ISD generate weaker urinary flow rates and detrusor pressures during urodynamic voiding studies. These patients may therefore be at heightened risk for voiding dysfunction following anti-stress incontinence surgery.

References:
1. Am J Obstet Gynecol. 1997; 177: 303–310
2. European Urology. 2002; 42(6): 583–9

Presentation Number: 043

THE UTELITY OF URODYNAMICS IN REFRACTORY NOCTURNAL ENURESIS

M. ELMISSIRY, G. ABDELFATTAH ALI, H. BADAWY, A. ABDELKARIM, S. ELSALMY;
Alexandria Univ., Alexandria, Egypt.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Background & Objective:
Refractory enuresis is embarrassing both to the patient and the treating doctor. After failure of empirical treatment, the treating physician starts to investigate the patient by urodynamics. How far these patients would benefit from this invasive test in affecting their management and what is the suggested way of study in these patients were evaluated in the present study.

Methods:
Fifty six patients; 17 males and 39 females with age range of 5–30 years were included in the study after failure of multiple courses of medical treatment for nocturnal enuresis. Thirty patients underwent cystometrogram (CMG), uroflowmetry (UFM) and electromyogram (EMG), while 26 patients underwent Pressure/Flow/EMG studies.

Results:
Bladder filling abnormalities were found in 25 patients and included low bladder capacity in 55%, detrusor overactivity in 55% and hypocompliance in 72%. The new observation was that voiding dysfunction was found in a high percentage of the patients; where 70% of the patients who did UFM + EMG had detrusor sphincter dysenergia (DSD) and 67% of the patients who did P/F/EMG study had Bladder outlet obstruction.

Conclusions:
A large percentage of patients were diagnosed as having voiding dysfunction rather than primary nocturnal enuresis. This can be diagnosed by UFM + EMG as well as by P/F/EMG tests. UFM + EMG is preferred as a non invasive and physiological test. UFM alone may be misleading as the Qmax may be normal in spite of presence of overactive external sphincter especially in females. The use of alpha adrenergic blockers may be of benefit in treating these patients.

Presentation Number: 044

DIFFERENT URODYNAMIC PATTERNS IN FEMALE BLADDER OUTLET OBSTRUCTION: CAN URODYNAMICS ALONE REACH THE DIAGNOSIS?

M. ELMISSIRY, G. ABDELFATTAH ALI;
Alexandria Univ., Alexandria, Egypt.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Background & Objective:
The diagnosis of bladder outlet obstruction (BOO) in females is still controversial. We studied the different urodynamic patterns of voiding cystometry in females with BOO and correlated them with clinical presentation and residual urine in a trial to reach a more precise method to diagnose female BOO.

Methods:
Over the last 3 years, 92 females with a mean age of 48.3± 14.28 years suffering from lower urinary symptoms underwent pressure flow studies. They were divided into 4 groups according to cutoff value of Q_{max} 15 ml/s and P_{det} Q_{max} 30 cmH_2o. Group A (32 patients) and group B (22 patients) had Q_{max}>15 ml/s and $P_{det}Q_{max}$<30 cmH_2o or >30 cmH_2o respectively. Group C (18 patients) and group D (20 patients) had Q_{max}<15 ml/s and $P_{det}Q_{max}$<30 cmH_2o or>30 cmH_2o respectively.

Results:
Group A patients suffered from irritative symptoms only and was used as a control group, while groups B, C & D suffered mainly from obstructive symptoms. The mean Q_{max} for group A, B, C, and D was 21.8, 21.9, 9.9 and 10.8 ml/s respectively while the mean P_{det} Q_{max} for the same groups was 20.8, 40.4, 18.7 and 48.7 cmH_2o respectively. Residual urine was normal in groups A & B but high in groups C (49.33±86.23 ml) and D (69.95±115.63 ml).

The results of groups B, C & D were compared with the control group A. The 3 groups (B, C and D) had significant difference with group A in the P_{ves} value (p<0.001). As regards Q_{max}, maximum voided volume and residual urine, only group C and D had significant difference with group A (p<0.001). Regarding the P_{det} $Q_{max,}$ only group B and D had significant difference with group A (p<0.001).

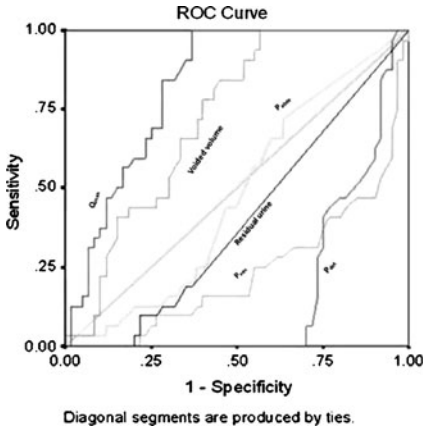
When ROC curves were done for all variables, both Q_{max} and maximum voided volume showed higher sensitivity to detect BOO (97% & 88% respectively). On the other hand, specificity was high for Q_{max} and residual urine volume (63 and 72% respectively).

By interpreting the clinical and urodynamic results, we can say that group A patients were obviously unobstructed, group D

patients were obviously obstructed while those in group B & C were equivocal. Group B might have compensated obstruction (flow is still normal with no residual urine but high voiding pressure). Group C can be considered as de-compensated obstruction (low flow with a normal or low voiding pressure but high residual urine).

Conclusions:

Bladder outlet obstruction in females cannot be diagnosed on the urodynamic bases alone; clinical presentation and residual urine volume should be all considered. The possibility of BOO in females is high with low flow, small voided volume and high residual urine.



Presentation Number: 045

CAN PREOPERATIVE URODYNAMIC VIODING PARAMETERS PREDICT POSTOPERATIVE VOIDING DYSFUNCTION IN PATIENTS WITH INTRINSIC SPHINCTER DEFCIENCY UNDERGOING A SUBURETHRAL SLING?

C. K. GROSS[1], D. R. KARP[1], A. L. SMITH[2], V. C. AGUILAR[1], G. W. DAVILA[1];

[1]Cleveland Clinic Florida, Weston, FL, [2]Cleveland Clinc Florida, Weston, FL.

Consent obtained from patients: Yes

Level of support: Investigator initiated, no external funding

Work supported by industry: No

Objectives:

To determine if urodynamic voiding parameters can help predict postoperative voiding dysfunction following sling placement in patients with intrinsic sphincter deficiency (ISD).

Background:

Voiding dysfunction is a common complication after synthetic slings. ISD has been shown to affect bladder emptying but it is unclear how this influences voiding following sling placement for stress incontinence.[1]

Methods:

This was a retrospective study performed at a single institution between January 2008 and December 2010 in which preoperative and postoperative voiding parameters were compared in patients with ISD. ISD was defined as maximal urethral closure pressure ≤20 cm H_20, and/or Valsalva leak point pressure ≤60 mm H_20. Patients with a diagnosis of detrusor overactivity were not excluded from this review.

Voiding dysfunction was defined as a persistent post void residual (PVR) greater than 100 mL at 2, 6 week and at last follow up visits or any patient needing medical or surgical treatment for persistent voiding dysfunction. Preoperative voiding was evaluated with uroflowmetry and pressure flow studies including detrusor pressure at peak flow, maximum and mean flow rates, and PVR. Prolonged postoperative catheterization >7 days was also analyzed. Any postoperative medical or surgical treatment for voiding dysfunction throughout their postoperative course was recorded.

Statistical analysis was performed using JMP_R 8.0. Comparisons were made using the Wilcoxon signed-rank test and Chi-square/ Fisher exact test where appropriate. A value of $p<0.05$ was considered statistically significant.

Results:

During the study period, 98 patients with a diagnosis of ISD underwent incontinence surgery. Mean age was 70.1 ±12.1 years, median parity was 3 (1–10), and 71 (72.4%) were postmenopausal (Table 1). Sling types were 17 (17.3%) transobturator, 14 (14.3%) retropubic mid-urethral, and 67 (68.4%) pubovaginal. A total of 77 women had suprapubic or Foley catheters in at the time of hospital discharge, and the mean time to catheter removal was 7.5±3.97 days (Table 2).

Postoperatively, 14 (14.3%) had voiding dysfunction and 84 (85.7%) did not. Mean follow-up was greater in the voiding dysfunction group (50.3 vs. 26.7 weeks, $p=0.01$). Preoperative urodynamic data including voiding detrusor pressure at peak flow, peak and mean flow rates, and post-void residual were not significantly different between the two groups (Table 3).

Conclusion:

In this study population of elderly patients with ISD, the incidence of postoperative voiding dysfunction was low despite a high rate of retropubic bladder neck slings. Preoperative urodynamic voiding parameters are not reliable indicators for the development of postoperative voiding dysfunction.

References:

Med Sci Monit, 2006; 12(8):345–50

*TABLE 1: Patient Characteristics**

	ISD $n=98$
Age	70.5±12
Postmenopausal Status	71 (72)
Parity	3 (0–10)
Previous Hysterectomy	38 (39)
Prior Incontinence Procedure	6 (6)
Prior Prolapse Surgery	11 (11)
Concomitant Prolapse Surgery	66 (67)
Sling Type	
•	
Transobturator	17 (17.3)
•	14 (14.3)
Retropubic	67 (68.3)
•	
Pubovaginal	

*expressed as mean ± SD and n (%) where appropriate

*Table 2: Postoperative Voiding Characteristics**

	ISD n=98
2 week PVR (mL)	34.9±38.6
6 week PVR (mL)	44.3±43
Catheter Placement	77 (78.5)
Catheter Removal (days)	7.5±3.97

*expressed as mean ± SD and n (%) where appropriate

*Table 3: Preoperative voiding characteristics & intraoperative sling type**

	Voiding Dysfunction n=14	No Voiding Dysfunction n=85	*p-value*
Age (years)	70.4±13.6	70.4±11.2	*0.9888*
Detrusor Pressure (cm H20) (Qmax)	13.2±11.7	12.0±10.4	*0.7700*
Qmax (ml/sec)	15.8±6.3	15.4±6.4	*0.6927*
Qmean (ml/sec)	6.32±3.1	6.6±3.6	*0.9101*
Post Void Residual (mL)	84.2±101.5	47.9±49.1	*0.3547*
Valsalva voiding	3 (21.4)	19 (22.6)	*0.92*
Detrusor Overactivity	3 (21.4)	23 (27.4)	*0.6405*
Sling Type			
•			
Retropubic	13 (92.9)	67 (80.7)	*0.2693*
•	11 (78.5)	56 (66.7)	*0.3752*
Pubovaginal			

*expressed as mean ± SD and n (%) where appropriate

Presentation Number: 046

SURGICAL MANAGEMENT OF RECURRENT PELVIC ORGAN PROLAPSE AFTER MESH PROLAPSE SURGERY

C. SCHMID[1], P. O'ROURKE[2], C. MAHER[3];
[1]RBWH Brisbane Urogynaecology, Brisbane, Australia, [2]Queensland Inst. of Med. Res., Brisbane, Australia, [3]RBWH Brisbane & Wesley Urogynaecology, Brisbane, Australia.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
A prospective case-series to assess and evaluate the surgical management of recurrent pelvic organ prolapse (POP) after mesh prolapse surgery.

Background:
Both incidence and prevalence for prolapse surgery increases with age. The estimated lifetime risk of American women to undergo at least one surgical intervention by the age of 80 is 6.3% with 30% requiring subsequent surgery. While this data does not directly relate to recurrent prolapse after prior mesh prolapse surgery we will with the increasing utilisation of polypropylene mesh in prolapse surgery encounter this problem more frequently. To date there is little or no clinical information on how to address recurrent prolapse after mesh failure and the success of any further surgical intervention undertaken.

Methods:
All patients between March 2010 and December 2010 undergoing prolapse surgery for recurrent POP after mesh prolapse surgery were included and surgical outcomes assessed by comparing pre and post-operative (6 weeks and 6 months) POP-Q findings and validated Queensland Female Pelvic Floor Questionnaire (QFPFQ). Patient satisfaction was evaluated utilising the PGI-I (Patient Global Impression of Improvement) at final review. Ethics committee approval was obtained.
Those with prior vaginal mesh surgeries underwent laparoscopic sacral colpopexy except those with a uterus present who underwent vaginal hysterectomy, mesh augmented repair anteriorly and native tissue posterior repair with vault suspension. After failed laparoscopic sacral colpopexy vaginal surgery was indicated for level 2 delancey defects. Those with urinary stress incontinence or occult incontinnece with prolapse reduction underwent concomitant colposuspension laparoscopically or TVT-O in the vaginal surgery group.

Results:
Twenty patients were identified with a recurrent prolapse after prior mesh surgery. The mean time of recurrence of the prolapse which required surgical intervention was 4.2 years and the mean follow-up time was 6.3 months (Table 1).
The initial mesh prolapse surgery included: anterior vaginal polypropylene mesh (12), posterior polypropylene mesh (9), a total mesh repair (3), sacral colpopexy (2) and collagen (1) mesh was inserted. Two polypropylene vaginal mesh surgeries for recurrent POP were performed in 4 and 1 had three prior vaginal mesh surgeries. In 18 women (90%) the recurrent prolapse occurred in a site of prior mesh surgery. A laparoscopic sacral colpopexy was performed in 60% (12), a vaginal hysterectomy with an anterior vaginal polypropylene mesh, posterior vaginal repair and sacrospinous colpopexy in 30% (6) and a sacrospinous colpopexy with a posterior vaginal native tissue repair 10% (2). Concomitant TVT-O were performed in 4 patients and paravaginal repair/colposuspension in 10 patients respectively. No significant peri-operative complications occurred.
Intermittent self-catheterizing was required in 40% due to postoperative voiding dysfunction for a maximum of 4 weeks. At mean review of 6.3 months conducted not be surgeon no mesh erosion was present. The QFPFQ showed that the bladder (p=0.003) and prolapse (p<0.001) domain scores improved significantly however no changes were seen in bowl (p=0.31) and sexual function (p=0.09) domains. POP-Q postoperatively demonstrated significant improvement in Aa, Ba, C, Ba, Bp with no change in TVL as seen in Table 2. The patient evaluation of the surgery using the PGI-I indicated that 90% of the patients rated the outcome as "very much" or "much better" whilst only 10% have "not changed" or "worse". Two patients who underwent vaginal surgeries are booked to undergo further prolapse surgery.

Conclusion:
This prospective case series shows demonstrates that recurrent prolapse surgery after failed mesh surgery is feasible and safe.

Clinicians need a variety of surgical options to address this challenging problem.

Table: 1 Demographic data

	N	Minimum	Maximum	Mean	Std. Deviation
age at review	20	43	73	61.80	9.018
BMI	20	25	34	28.40	2.683
Operation Time/min	20	45	120	82.25	18.812
Blood loss/ml	20	100	300	140.00	57.583
Admission time/d	20	2	12	3.65	2.207
Time of recovery/ weeks	20	2	12	5.85	2.110

Table 2: POP-Q changes pre-and postoperatively

Mean	Std. Deviation	Sig. (2-tailed)	.000
Ba/pre - Ba/post	2.550	2.012	.000
C/pre - C/post	6.250	4.833	.000
D/pre - D/post	5.850	4.682	.000
TVL/pre - TVL/post	.200	.410	.042
GH/pre - GH/post	.025	.343	.748
PB/pre - PB/post	.025	.343	.748
Ap/pre - Ap/post	1.400	1.465	.000
Bp/pre - Bp/post	1.450	1.504	.000

Presentation Number: 047

UTERINE PRESERVATION: EARLY EXPERIENCE WITH VAGINAL SACROSPINOUS SUSPENSION USING POLYPROPYLENE MESH

G. GHONIEM, M. A. CRITES, B. ALMOSAIEED;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Restoration of normal anatomy and pelvic floor function is the primary goal of reconstructive pelvic surgery.

Background:
Sacrospinous suspension is generally a highly effective and well-tolerated surgical treatment for uterovaginal prolapse. Traditionally, hysterectomy was offered as part of uterine prolapse repair. Mesh use for sacrospinous suspension is a relatively new procedure that can be performed with uterine preservation and is expected to have comparable outcomes. We present our early experience with patients who had vaginal sacrospinous suspension with uterine preservation using polypropylene mesh.

Methods:
Patients with uterovaginal prolapse were evaluated in the clinic. Detailed history and physical examination was performed and uterovaginal prolapse was assessed with the modified POP-Q staging system. The total vaginal length (TVL) and post void residual (PVR) urine were also recorded. All patients underwent uterine screening for pathology by Pap smear and pelvic ultrasound. All patients were asked to complete validated Questionnaires pre-operatively and included the Urogenital Distress Inventory −6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), and AUA Quality of Life (QoL).

Patients were admitted on the day of the procedure and vaginal packing and indwelling catheter were removed at 6 am the following day. Surgical details for each patient were evaluated and recorded. These details included: Each patient's pre and post-operative hemoglobin values, estimated blood loss (EBL) intra-operatively, and length of hospital stay.

The patients were followed in the clinic post-operatively at 6 weeks. Follow up evaluation included: physical examination to assess prolapse stage, PVR, TVL, presence of erosion, and presence of pain. Patients were asked to complete the same pre-operative questionnaires with the addition of a Visual Analog Scales (VAS) of Satisfaction and Cure.

Results:
Twelve patients (12) underwent vaginal sacrospinous suspension using polypropylene mesh with uterine preservation at our institution. The mean age of the patients was 62.2 years. The mean intra-operative blood loss was 183.8 cc, mean pre-operative hemoglobin was 12.7 g/dL, mean post-operative hemoglobin was 10.0 g/dL, and mean hospital stay was 1.3 days. Table I illustrates prolapse results pre and post-operatively.

Table I. Degree of Pelvic Organ Prolapse

Pre-operative						**6-week follow up**				
Stage	**0**	**1**	**2**	**3**	**4**	**0**	**1**	**2**	**3**	**4**
Anterior	0	0	2	10	0	8	3	0	0	0
Apical	0	3	8	1	0	12	0	0	0	0
Posterior	1	9	1	1	0	10	2	0	0	0

The mean PVR pre-operatively was 146.6 mL and 52.1 mL at 6 weeks. The mean TVL pre-operatively was 9.1 cm and 11.5 cm at 6 weeks. Table II illustrates the results of the validated questionnaires. The mean post-operative VAS of Satisfaction and Cure was 81.8% and 80% respectively at 6 week follow up.

Table II. Patient Evaluation

Questionnaires	**Pre-operatively**	**6 week follow up**
UDI-6	**9.5**	**3.82**
IIQ-7	**8.5**	**2.25**
QoL	**4.3**	**1.27**

One patient had mesh exposure that was discovered at 6-week follow up and was repaired without difficulty. This appeared to be secondary to a short anterior vaginal wall. One patient had urinary retention post-operatively that resolved with 7 days of catheter drainage. There were no incidences of wound infection, DVT,

bladder or rectal perforation, dyspareunia, or persistent pain diagnosed for any patient postoperatively.

Conclusions:

Early experience with vaginal sacrospinous suspension using polypropylene mesh in conjunction with uterine preservation resulted in favorable outcomes that boasted effective results with high satisfaction, low-volume blood loss, minimal hospital stay, and low incidence of complications.

Presentation Number: 048

TREATMENT OF RECURRENT VAGINAL PROLAPSE WITH THE PINNACLE PELVIC FLOOR REPAIR KIT

L. RICCI[1], R. BACCICHET[2], A. SOMMACAL[3], V. BRUSATI[3], M. MESCHIA[3], L. SPREAFICO[1];

[1]Ospedale E Franchini, Montecchio Emilia, Italy, [2]Ospedale Ca Foncello, Treviso, Italy, [3]Ospedale G Fornaroli, Magenta, Italy.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objectives:

To determine the morbidity and efficacy of the PinnacleTM pelvic floor repair kit for women with recurrent anterior and apical vaginal prolapse.

Background:

Over the last decade, mesh augmented surgical repair is being increasingly used, mainly for secondary procedures. Recurrent prolapse suggest poor tissue quality or an unsuccessful earlier intervention therefore is more justifiable to use foreign material for vaginal repair in these patients than in those undergoing primary surgery. The Pinnacle pelvic floor repair kit is designed to offer level I support which provides suspension of the vaginal apex to the sacrospinous ligament in addition to level II support. The system comprises of:

-A central low density and lightweight polypropylene mesh designed to cover pelvic floor defects

-Four lateral legs of the same material secured to the central part by polypropylene sutures, covered by plastic sheath, and ending with polypropylene sutures to allow passages of the legs through anatomical key points.

-A Capio device for sutures carrying through the sacrospinous ligament and arcus tendineous fascia pelvis

Material and methods:

This is a case series of women with ≥ stage II recurrent anterior vaginal wall prolapse associated with various degree of apical descent. The pre-operative evaluation included a detailed medical and surgical history, symptoms assessment and pelvic examination. At physical examination, pelvic floor defects were determined using the Pelvic Organ Prolapse Quantification System. Measurements were made at different vaginal sites (anterior/posterior vagina and cuff/cervix) with the patient recumbent and straining down. A 10-grade visual analogue symptoms scale (VAS) was used to quantify subjectively the patients' perception of prolapse symptoms severity. The primary objective of the study was to evaluate the intra and early post-operative morbidity and rate of genital prolapse recurrence (measured at any vaginal site) as well as rate of late complications. Anatomic outcomes were defined according to the ICS recommendations. All patients were informed about the study and procedure and gave their informed consent.

Details of the surgical procedure are shown in the associated video

Results:

Between November 2009 and June 2010, 11 women agreed to participate and were included in the study. The mean age was 66± 10 years and the mean BMI was 27.5±5.1. All subjects had undergone previous prolapse surgery including anterior midline repair and most, except one, received,at that time, a concomitant vaginal hysterectomy. The mean pre-operative VAS score was 8.2±1.7. At physical examination there were 5 and 6 subjects respectively with stage II and III anterior prolapse and 9 and 2 with stage II and III apical prolapse. A posterior midline repair was associated in 6 subjects. Bladder injury occurred in one patient and another one experienced excessive bleeding while entering the paravesical space. Both cases were managed successfully and the procedure was completed with the insertion of the Pinnacle^{TM} kit. No patients had urinary retention or voiding difficulty and the average hospital stay was 3.2±0.6 (3–5)d. Patients underwent the scheduled 6 and 12 visits with a mean follow-up time of 9.3±3.1 months. The post-operative VAS score was 2.1± 1.7 ($p<0.01$ when compared with pre-op score). Pre and post-operative prolapse staging is shown in table 1. Post-operative complications included: 2 de novo SUI and 2 de novo UUI. Moreover there was one patient complaining of de novo dyspareunia and one of severe pelvic pain due to retraction of the implanted mesh at the level of both sacrospinous ligaments.

Conclusions:

Our data show that transvaginal mesh repair of recurrent genital prolapse with the Pinnacle^{TM} pelvic floor repair kit achieves satisfactory anatomic results in almost 90% of patiens. The shrinkage phenomenon with associated pelvic pain is a well known complication of all synthetic materials and kits and the surgical management of these cases may be challenging even for well trained and expert pelvic surgeons.

Table 1. Pre- and post-operative prolapse staging according to the POP-Q

Pre-OP, *n*=11	0	I	II	III	IV
Anterior	0	0	5 (45%)	6 (55%)	0
Apical	0	0	9 (82%)	2 (18%)	0
Posterior	2 (18%)	3 (27%)	5 (45%)	1 (9%)	0
Post-Op, *n*=11					
Anterior	5 (45%)	5(45%)	1(9%)	0	0
Apical	8 (73%)	3(27)	0	0	0
Posterior	9 (82%)	2 (18%)	0	0	0

Presentation Number: 049

THE ELEVATE^{TM} ANTERIOR SYSTEM FOR THE TREATMENT OF ANTERIOR VAGINAL WALL PROLAPSE

L. RICCI[1], R. BACCICHET[2], S. BERTINI[3], G. ROSSI[3], L. SPREAFICO[1], M. MESCHIA[3];

[1]Ospedale E Franchini, Montecchio Emilia, Italy, [2]Ospedale Ca Foncello, Treviso, Italy, [3]Ospedale G Fornaroli, Magenta, Italy.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objectives:
To determine the morbidity and short-term efficacy of the Elevate™ anterior system for anterior and apical prolapse repair.
Material and methods:
This is an ongoing multicenter prospective study. Women with ≥ stage II anterior vaginal wall prolapse were selected to receive a transvaginal prosthetic anterior repair by means of the Elevate™ anterior system, an innovative device for the treatment of cystocele and associated apical prolapse. The pre-operative evaluation included a detailed medical and surgical history, symptoms assessment and pelvic examination. At physical examination, pelvic floor defects were determined using the Pelvic Organ Prolapse Quantification System. Measurements were made at different vaginal sites (anterior/posterior vagina and cuff/cervix) with the patient recumbent and straining down. A 10-grade visual analogue symptoms scale (VAS) was used to quantify subjectively the patients' perception of prolapse symptoms severity. The primary objective of the study was to evaluate the intra and early post-operative morbidity and rate of genital prolapse recurrence (measured at any vaginal site) as well as rate of late complications. Anatomic outcomes were defined according to the ICS recommendations. All patients were informed about the study and procedure and gave their informed consent.
Surgical technique: The Elevate™ system comprises of:
• Low density and lightweight mesh anatomically designed to cover the anterior area
• Fixating arms to allow accurate mesh placement and intra-operative tensioning
• Apical and anterior needles to allow fixation of the mesh into the sacrospinous ligament and obturator internus muscle respectively
Details of the surgical procedure are shown in the associated video
Results:
Between June 2010 and January 2011, 27 women agreed to participate and were included in the study. The mean age was 64±8.9 years and the mean BMI 27.2±4.3. Nineteen subjects had undergone previous hysterectomy of whom 10 for prolapse repair and 9 for other benign conditions.. The mean VAS score was 8.4±1.2. A posterior midline repair was associated in 10 subjects and a mid-urethral sling in one. There were no intra-operative complications such as visceral injury or heavy bleeding. Two and three patients respectively had urinary retention and voiding difficulty that resolved spontaneously within 10 days from surgery. The average hospital stay was 3.8±1.7 d.
Women with at least three months follow-up were considered for the analysis of outcomes. There were 22 women available for the analysis with a mean follow-up time of 5.3±2 months. The mean post-operative VAS score was 1.5±1.7 ($p<0.001$ when compared with pre-op score). Pre and post-operative prolapse staging is shown in table 1. Post-operative complications included: 3 de novo SUI and 2 de novo UUI. No mesh exposure or de novo dyspareunia was recorded
Conclusions:.
Our preliminary data suggest that transvaginal mesh repair of genital prolapse with the Elevate™ anterior system is a promising technique easy to accomplish. Longer follow-up is needed to address the long term efficacy and complications rate.

Table 1. Pre- and post-operative prolapse staging according to the POP-Q

Pre-OP, *n*=27	0	I	II	III	IV
Anterior	0	0	9 (33%)	16 (60%)	2 (7%)
Apical	2 (7%)	13 (48%)	8 (30%)	3 (11%)	1 (4%)
Posterior	10 (37%)	13 (48%)	3 (11%)	1 (4%)	0
Post-Op, *n*=22					
Anterior	13 (59%)	9 (41%)	0	0	0
Apical	21 (95%)	1(5%)	0	0	0
Posterior	19 (86%)	3 (14%)	0	0	0

Presentation Number: 050
ULTRASOUND GUIDED AUTOLOGOUS MYOBLAST INJECTIONS INTO THE EXTRINSIC URETHRAL SPHINCTER- TISSUE ENGINEERING FOR TREATMENT OF STRESS URINARY INCONTINENCE
M. BLAGANJE, A. LUKANOVIć;
Univ. Med. Ctr. Ljubljana, Ljubljana, Slovenia.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: Yes

Objective:
Muscle derived stem cells as a personalized medicine for the regenerative repair of the deficient extrinsic urethral sphincter offer a novel minimally invasive approach to treatment of stress urinary incontinence (SUI). The non-migratory property and fusion potential of autologous myoblasts requires precise cell application and imaging of the treated structure. This being one of the first clinical applications of myoblasts as a single-cell-line treatment for SUI, our objective was to investigate the efficacy of transurethral ultrasound-guided autologous myoblast injections into the external urethral sphincter in female patients with SUI.
Background:
The urethral sphincteric complex is formed by the inner smooth and outer striated sphincter muscles of the midurethra. The functional integrity of the voluntarily controlled striated extrinsic sphincter plays a pivotal role in maintaining continence. The functional and morphological changes of the rhabdosphincter are observed after vaginal delivery, surgical injury and as part of the aging process. There are numerous ways to treat SUI, but active

function can only be improved by physiotherapy. Animal models have paved a way to clinical trials using autologous muscle derived stem cells—myoblasts, a possible novel single-cell-line tissue engineering treatment option, to restore active function through tissue regeneration of the rhabdosphincter.

Methods:

With National Medical Ethics Committee approval, Agency for Medicinal Products and Medical Devices approval and informed consent 38 patients with primary symptoms of SUI, normal detrusor activity on filling cystogram and bladder capacity of over 300 ml, who failed prior non-invasive treatment were recruited. Exclusion criteria were marked hypermobility, uterine or vaginal descensus and previous anti-incontinence surgery. Skeletal muscle tissue biopsy was obtained from a small open cut biopsy of the non-dominant upper arm and shipped to a remote cell-processing laboratory for isolation and expansion of myoblasts. Suspension of autologous myoblasts was injected in local anesthesia under transurethral ultrasound guidance according to a standard pattern directly into the extrinsic urethral sphincter through a combined transurethral ultrasound device. To enhance cell integration patients underwent a cycle of electrical stimulation (ES) after myoblast implantation. To avoid bias an identical cycle of ES was completed before myoblast injection. Patients were evaluated at baseline and at completion of ES cycles preinjection and at 6 weeks postinjection. Urinary incontinence episodes (UIE) and the amounts of leaked urine measured semiqantitative (UIS) were assessed from a 3-day voiding diary. Quality of life (as assessed by I-QoL) and Visual Analog Scale (VAS) were also assessed. Pre- and postinjection values were compared. The postinjection interview included the modified Patient Global Impression of Improvement (PGI-I).

Results:

38 female patients (mean age 52±11.2 years) were treated. One subject was lost to post-injection follow-up due to her other obligations.

The median pre-injection and post-injection UIE were 12 (range 1–35) and 5 (range 0–33), respectively ($p<0.0001$). The median pre-injection and post-injection UIS scores were 18.5 (range 2–49) and 5 (range 0–33), respectively ($p<0.0001$). VAS and I-QoL scores were both significantly improved postoperatively ($p<0.0001$). PGI-I assessment revealed 5 of 37 patients (13.5%) cured and 29 of 37 patients (78.4%) improved at 6 weeks postinjection. No serious adverse events or perioperative complications were noted.

Conclusions:

The transurethral ultrasound guided injection of autologous myoblasts proved itself an effective and safe new minimally invasive therapeutic modality of female SUI and a promising treatment for the future.

References (optional):

Presentation Number: 051

VAGINAL INVAGINATION

C. SCHMID[1], P. O'ROURKE[2], C. MAHER[3];
[1]Royal Brisbane Urogynaecology, Brisbane, Australia, [2]Queensland Inst. of Med. Res. (QIMR), Brisbane, Australia, [3]Royal Brisbane & Wesley Urogynaecology, Brisbane, Australia.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

Observational study to define and describe vaginal invagination identified at vaginal prolapse surgery and to report the surgical outcome after releasing the invaginated vaginal tissue.

Background:

We identified our first case of invaginated vaginal tissue when at vaginal surgery a localised area of fixed vaginal tissue at the vault that limited access to the pelvic sidewall. Mobilisation of the fixed portion of the vagina provided an easier and safer access to the pelvic sidewall. More suprisingly, the mobilisation resulted in the release of increased vaginal tissue that could be incorporated into the repair. This single case instigated this prospective evaluation.

Methods:

Twenty-five consecutive patients with a vaginal invagination were identified intra-operatively at the time of vaginal prolapse surgery. The vaginal invagination was identified and the area of vaginal tissue released was quantified. Furthermore we sought to determine the impact that this finding and release may have upon surgical outcomes by comparing pre- and post-operative (6 weeks and 6 months) POP-Q findings and validated Queensland Female Pelvic Floor Questionnaire (QFPFQ). The PGI-I (patient global impression of improvement) completed at final review. Ethics committee approval was obtained.

Results:

Thirteen percent of women (25 out of 180) undergoing vaginal prolapse surgery between May 2010 and December 2010 had a vaginal invagination identified. Although no patients were lost to follow-up two refused to participate and three were unavailable for examination at 6 months due to travel from interstate. The mean age was 63 years, parity 3 and BMI 29 (Table 1). All had undergone prior vaginal surgery with 60% undergoing vaginal hysterectomy (VH) alone, 16% VH and repair, 16% total abdominal hysterectomy and repair, 4% vaginal repairs and 4% a sacrospinous hysteropexy. Concomitant surgery included sacrospinous colpopexy with repair (88%), sacrospinous hysteropexy (8%) and vaginal hysterectomy and repair (4%). Intraoperative assessment showed that the invagination was characterised by a tight fixed and tethered portion of vaginal mucosa at the vault which was unilateral in 11 (44%) and bilateral in 14 (56%). The mean gain of vaginal mucosa after releasing entrapped tissue was 3.5 cm^2. Increased blood loss (>300 ml) was seen in 10% however no transfusions were required.

The QFPFQ showed that the bladder, bowl and prolapse domain scores improved significantly postoperatively ($p<0.05$) however no change was seen in sexual function domain ($p=0.175$). Dyspareunia rate could not be accurately assessed as many patients had not returned to regular sexual activity.

Table 2 documents pre- and post POP-Q changes.

The patient evaluation of the surgery using the PGI-I indicated that 95% of the patients rated the outcome as "much better" or "very much better".

Table 1: Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Follow up/months	23	1	17	6.30	5.555
Operation Time/min	23	60	150	90.50	24.110
Blood loss/ml	23	90	600	239.50	124.794
Distance of gained mucosa/cm²	23	2	5	3.58	.634
Admission time/days	23	2	12	5.10	2.075
Recovery time/weeks	23	2	24	6.40	4.535

Table 2

	Mean	Std. Deviation	Sig. (2-tailed)
Ba/pre - Ba/post	1.3500	1.4609	.001
C/pre - C/post	5.8250	3.4154	.000
D/pre - D/post	6.1250	3.3556	.000
TVL/pre - TVL/post	.0750	1.1035	.764
Bp/pre - Bp/post	2.5500	1.5035	.000

Conclusions:
Vaginal invagination occurs when the vaginal mucosa becomes folded and entrapped on itself. Vaginal examination is characterised by a fixed and tight area of vaginal mucosa occurring universally at the vault and can be unilateral or bilateral. This is always seen after surgery on the vagina with hysterectomy being the most common surgery and vaginal hysterectomy the most frequent type of hysterectomy. The identification and release of the invaginated vagina ensures an easier and safer access to the pelvic sidewall and increases vaginal mucosal area. Further evaluation is required to determine if identification and release of the vaginal invagination will improve patient outcomes following surgery.

Presentation Number: 052

TRANSOBTURATOR VERSUS SINGLE INCISION SLINGS IN WOMEN WITH STRESS URINARY INCONTINENCE: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

A. L. SMITH, P. CASTILLO, D. KARP, C. GROSS, G. DAVILA, V. C. AGUILAR;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To compare outcomes of transobturator to single incision slings for the treatment of stress urinary incontinence (SUI).
Background:
Single incision slings avoid retropubic or groin needle passage. Although transobturator slings have demonstrated success rates ranging from 80% to 96%, data on single incision slings is limited with recent randomized trials showing higher failure and reoperation rates in the mini-sling groups[1]. There are currently few prospective studies comparing transobturator to single incision slings, although many retrospective and cohort studies have reported similar cure rates at short term follow-up.
Methods:
This is an interim analysis of a prospective, randomized non-blinded study performed at a single institution. Patients with urodynamically proven SUI were offered participation and underwent transobturator (Monarc™, American Medical Systems, Minnetonka MN) or single incision (MiniArc™, American Medical Systems, Minnetonka MN) sling placement between November 2008 and January 2011. Patients with prior anti-incontinence surgery, a urodynamic diagnosis of intrinsic sphincter deficiency or low pressure urethra (Valsalva leak point pressure <60 and/or maximal urethral closure pressure <40) and mixed incontinence with a predominance of detrusor overactivity were excluded. Preoperatively each patient completed the short forms of the Urinary Distress Index (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and International Consultation on Incontinence Questionnaire (ICIQ) and a 3-day voiding diary.
Allocation to treatment group was performed by a computer generated randomization scheme and both surgeon and patient were blinded to allocation until the onset of anesthesia. Postoperative outcomes were assessed at 12 weeks, 24 weeks and then yearly. The primary outcome measure was presence or absence of urinary leakage during standardized cough stress test (CST) at 250 ml. Secondary outcomes included intraoperative data, subjective complaint of recurrent/persistent SUI, self-assessment of cure, and response to validated questionnaires. Complications including voiding dysfunction, mesh exposure and need for repeat incontinence treatment were noted.
A power calculation confirmed that 40 patients in each group were necessary to achieve 80% power. An interim analysis was planned for when half of the sample size reached their 6 month postoperative visit.
Statistical analysis included the student *t*-test, wilcoxon rank sums, and Chi-square/Fisher's exact tests.
Results:
81 patients were randomized with 38 patients undergoing Monarc and 43 patients MiniArc. Demographics, symptoms of stress incontinence severity, urodynamic parameters and baseline questionnaire scores were similar between groups. Rates of concomitant prolapse surgery did not differ among groups. The Monarc group had a longer sling operative time (10.4±4.0 min vs. 7.6± 4.6 min, $p<0.001$) and greater estimated blood loss (30.4± 21.7 mL vs. 23.6±22.7 mL, $p<0.05$).
Mean follow-up was similar at 33.7±22.9 and 31.1±21.9 weeks respectively. There was no difference in the primary outcome with 5 (21%) Monarc patients having a positive CST and 6 (25%) MiniArc patients ($p=0.73$). There was no difference in self assessment of cure (79% vs. 67%, $p=0.3$) or subjective report of recurrent/persistent SUI (29% vs. 37.5%, $p=0.54$). Postoperative subjective and objective urinary outcomes did not differ (Table 1). 2 patients in each group desired re-treatment for symptomatic SUI. Postoperative complications included one mesh erosion in each

group and 1 MiniArc sling transection due to bladder outlet obstruction.

Table 1: Postoperative secondary outcome measures

	TO (Monarc) *n*=24 (63%)	SI (MiniArc) *n*=24 (56%)	p-value
Self assessment "Cured/GI"	19 (79%)	16 (67%)	0.3
Subjective SUI	7 (29%)	9 (37%)	0.54
Inc. episodes/day	0.5±1.14	0.8±1.5	0.52
Pad usage/day	0.46±0.8	0.29±0.7	0.36
Voids/day	5.6±2.1	5.9±1.4	0.67
Urgency			
•	6 (25%)	3 (12.5%)	0.3
De novo	3 (12.5%)	0	0.07
PVR	37.1±32.2	30.3±33.2	0.3
IIQ-7			
UDI-6			
•			
Q3 (median & range)			
ICIQ			
SUI episodes on 3 day diary	4.5±14.7	7.1±13.5	0.06
	11.4±15.3	14.5±13.9	0.3
	0 (0–3)	0 (0–3)	0.3
	2.6±3.5	3.7±4.4	0.5
	4 (0–8)	1 (0–8)	0.8

Conclusion:
The MiniArc single incision sling decreases operative time and intraoperative blood loss and has similar efficacy to the Monarc transobturator sling for the treatment of stress urinary incontinence at 6 month follow-up.

References:
1. Female Pelvic Med Reconstr Surg 2010; 16(5) supp 2: S87.

Presentation Number: 053

TEN-YEAR FOLLOW-UP AFTER THE TENSION-FREE VAGINAL TAPE PROCEDURE (TVT)

T. AIGMUELLER[1], G. TRUTNOVSKY[1], K. TAMUSSINO[1], J. KARGL[2], A. WITTMANN[2], P. RISS[2], V. BJELIC-RADISIC[1];
[1]Med. Univ. of Graz, Graz, Austria, [2]Landesklinikum Thermenregion, Moedling, Austria.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The present study aimed to evaluate objective and subjective outcomes 10 years after TVT placement in patients operated at two centers that were early adopters of the procedure. We also evaluated late complications such as mesh erosions and reoperations, and prevalence of overactive bladder (OAB) symptoms.

Background:
In many areas in Europe the tension-free vaginal tape (TVT) procedure quickly displaced colposuspension, even though randomized trials had not been completed and long-term results, and possible sequelae, were unclear. In particular, long-term outcomes of alloplastic material close to the vagina, urethra and bladder was, and remains, a concern.

Methods:
210 patients who underwent a TVT procedure at the two participating units between 1999 and 2001 were invited for follow-up. All patients had undergone a standard retropubic TVT procedure as per the original description. All had clinically and urodynamically verified stress incontinence.
Evaluation at 10 years included history and clinical examination, assessment of residual urine, urodynamics (cystometry, midurethral closure pressure), a cough stress test, cystoscopy, interview with questions on pad use, and the self-administered Incontinence Outcome Questionnaire I-Quol-D.
The study protocol was approved by the Ethics Committee.

Results:
A total of 210 patients underwent a TVT placement in the years 1999–2001 at the two hospitals. The mean age at surgery was 60 years. The mean duration of follow-up was 115.7 months. Twenty-six patients died in the interim, unrelated to the TVT-procedure; 10 were too ill or frail for follow-up. Among the remaining study population of 174 patients, 16 could not be reached and 17 patients declined follow-up.
141 out of 210 patients were available for follow-up (67,1%). Subjective data were available from all 141 patients, a complete work-up was performed in 117 patients (117/210 patients, 55,7%).
51 patients (36%) underwent concomitant procedures with TVT.
At 10 years 11/141 patients (7.8%) had been reoperated for incontinence or reasons related to the TVT procedure: 4 patients underwent further anti-incontinence procedures. Six procedures were done to relieve voiding obstruction including 1 urethrotomy (120 months after surgery) followed by urethral mesh erosion. In one patient transurethral removal of bladder stones (30 and 42 month after TVT) and resection of mesh eroded into the bladder per laparotomy (50 month after TVT) was necessary.
In 117 patients evaluated clinically at 10 years, the clinical stress test was negative in 98 (84%), slightly positive in 10 (8.5%), and strongly positive in 5 (4.3%). Subjectively 57,4% (81/141) of patients considered themselves "cured", 23% (32/141) "improved", 6.4% (9/141) "unchanged", and 10,6% (15/141) "worse". 2,8% of patients (4/141) had repeat incontinence surgery in the interim.
At the time of follow-up there was one minor vaginal erosion detected (conservative treatment) but no additional erosion detected during cysto-/urethroscopy (*n*=117).
Preoperatively 54 of 141 patients (38%) reported urgency symptoms. 34 of these 54 (63%) were free of OAB symptoms at follow-up. Conversely, 17/83 (12%) patients without urgency preoperatively reported urgency at 10 years.

Conclusion: Our data indicate satisfactory objective and subjective cure rates 10 years after TVT placement. As in the other studies that have looked at long-term results after TVT placement, there does not appear to be a substantial rate of long-term or delayed erosions.
The objective continence rate exceeded the self-assessed cure rate (84% vs. 57%).
Interestingly, patients with mixed urinary incontinence preoperatively were frequently free of urgency whereas the rate of de novo urgency was 17%. The reoperation rate was modest (4%).

Presentation Number: 054

QUALITY OF FIXATION OF MINISLING AJUST

P. HUBKA, O. NANKA, A. MARTAN, K. SVABIK, R. EL-HADDAD, T. KOLESKA, P. DRAHORADOVA, J. MASATA;
First Faculty of Med., Charles Univ. in Prague, Czech Republic, Prague, Czech Republic.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
This study aimed to describe site of fixation and quality of fixation of the mini-sling Ajust™ and describe possible complications that might occur during this procedure.

Background:
The mini-slings were introduced as a modification of current treatment of female stress urinary incontinence in 2006. The concept of mini-slings was to eliminate foreign material, ease the procedure to be carried out under local anesthesia with achieving the same efficacy as previous generations of tension free vaginal tapes. However the first mini-sling TVT-Secur™ did not reach expectations of surgeons as the proper insertion was rare [1].
As different types of tapes and mini-slings have different fixation point it is essential to test whether correct fixation of the tape can be easily achieved and if the way of insertion poses risks of complications. The path of the tape might be influenced by the position of the legs [2], therefore we have examined different position of the legs. There is no published scientific evidence about insertion of the Ajust™ or about the efficacy of this method.

Methods:
This study was aimed to describe anatomical localization of the fixation tips of the Ajust™ mini-sling.
We have used a group of eleven formalin embalmed bodies with legs positioned in 30°flexion and 30°abduction and second group of five fresh frozen bodies with legs positioned as during the normal procedure. This would allow us to compare the results if they differ.
The insertion was performed by an urogynecologist well trained to carry out Ajust™ same as other previous methods. After insertion, abdominal dissection was carried out to describe the path and location of the fixation tips. Distances from important structures were measured.
The distance to the obturator nerve was considered as a primary safety parameter. For evaluation of the location we have considered the obturator membrane as the desired fixation point. Obturator muscles were considered as possible but less favorable fixation point. As a failure we have considered insertion without proper fixation - in example anchor was found prevesically. The placement into obturator internus muscle was considered as a less favorable fixation point due to the fact that is not as firm as the obturator membrane. Insertion of the tip deeply to obturator externus muscle was also considered as less favorable due to creating greater hole in the obturator membrane with the inserter and therefore the anchor might fail to hold properly.
For comparison of the groups we have used Student's *t* test and Mann–Whitney test, p value less than .05 was considered as statistically significant.

Results:
The mean distance from the anchoring point to the obturator nerve was in the group of formalin embalmed bodies 4.23 mm with the standard deviation 0.88 mm. The same distance in the group of fresh frozen bodies was 3.15 mm with the standard deviation 0.51 mm. There was statistically significant difference (*p* value less than .05) in distance from the obturator nerve comparing group of formalin embalmed and fresh frozen bodies based on Student's *t* test and Mann–Whitney test. No statistical significant difference was found in the distances from the obturator nerve while comparing the right and left side of each group.
In the group of formalin embalmed bodies the anchor was placed within the complex of obturator muscles and membrane in 19 cases out of 22. In two cases the anchor was not correctly positioned and was found in lesser pelvis prevesically. In one case the anchor was found in the sacrospinous ligament. In the group of fresh frozen bodies the anchor was placed within the obturator muscles or obturator membrane in nine cases out of ten and once we have found the anchor prevesically in lesser pelvis.

Conclusions:
The fixation point of the mini-sling Ajust™ was in all cases more than two centimeters away from the obturator nerve. Correct placement into the obturator membrane happened in more than 60% of the cases and in more than 85% of the cases the anchor was placed in obturator muscles or the membrane, which could be considered as acceptable. There was statistical significant difference in distance from the obturator nerve between group of formalin embalmed bodies and fresh frozen bodies—however to confirm this findings, we would need to increase number of bodies in each group.

References:
1. Hubka P, Masata J, Nanka O, Grim M, Martan A, Zvarova J (2009) Anatomical relationship and fixation of tension-free vaginal tape Secur. Int Urogynecol J Pelvic Floor Dysfunct 20:681–688
2. Hinoul P, Vanormelingen L, Roovers JP, de Jonge E, Smajda S (2007) Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O). Int Urogynecol J Pelvic Floor Dysfunct 18:1201–1206

Presentation Number: 055

PELVIC FLOOR MUSCLE TRAINING VERSUS VAGINAL CONES FOR POSTMENOPAUSAL WOMEN WITH STRESS URINARY INCONTINENCE: A RANDOMIZED, CONTROLLED CLINICAL TRIAL

V. S. PEREIRA, M. V. DE MELO, G. N. CORREIA, P. DRIUSSO;
Federal Univ. of São Carlos, São Carlos, Brazil.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The purpose of this study was to compare the effects of pelvic floor muscle training (PFMT) and vaginal cones (VC) with no treatment in postmenopausal women with stress urinary incontinence (SUI).

Background:
Physical therapy treatment uses different therapies with main objective the strengthening of pelvic floor muscles. Among them, the pelvic floor muscle training using vaginal cones seems to be effective by providing sense of slipping out and inducing a contraction of the pelvic floor muscles. However, the results of studies using vaginal cones are still inconclusive, since the scientific evidence is limited[1].

Methods:
This randomized controlled study included postmenopausal women, who complained of stress urinary leakage and never undergone at physical therapy for SUI before. Forty five women were allocated according to a computer generated randomization list in three groups: vaginal cones (VC), $n=15$; pelvic floor muscle training (PFMT), $n=15$; and control group (CG), $n=15$. The study was conducted at outpatient physical therapy department. Subjects on intervention groups were treated for 6 weeks with two weekly sessions of 40 min. Women of VC group carried out the pelvic floor muscle strengthening with vaginal cones. The CG did not receive any treatment during the corresponding time. They were evaluated before and after treatment for primary outcome (1 h pad test for urinary loss) and secondary outcomes (pelvic floor muscle pressure, quality of life with King's Health Questionnaire, and satisfaction with treatment). Participants and the physical therapist were not blinded. Forty one women completed the study and were included at the analysis (Age: 63,55± 10,45 years; Body Mass Index: 26,69±2,18 Kg/cm^2). The intragroup analysis was carried out with the Friedman tests and the pair-wise comparisons were carried out with the Wilcoxon signed-rank test. For the intergroup analysis before and after treatment the Kruskal-Wallis tests were used. Pair-wise comparisons were made with the Mann–Whitney test to compare the groups. This same test was carried out for the follow-up evaluation. The level of significance used was 0,05.

Results:
For primary outcome, there was a significant decrease of urinary loss in the VC ($p<0.001$) and PFMT ($p<0.001$) groups when compared the values at the end of treatment and at baseline. In the intergroup analysis, there were statistical differences between VC ($p<0,001$; effect size: −0,96; 95% confidence interval: 0,65–6,25) and PFMT ($p<0,001$; effect size: −0,93; 95% confidence interval: 0,46–6,52) groups and CG at the end of treatment. The pelvic floor muscle pressure, had a significant increase in the VC ($p<0.001$) and PFMT (p=0.001) groups. The intergroup analysis showed statistical differences between VC group and CG ($p<0.001$ effect size: 2,69; 95% confidence interval: 23,12–42,14) as well as between PFMT group and CG ($p<0.001$ effect size: 2,09; 95% confidence interval: 17,15–38,85) after treatment. Quality of life outcomes showed significant decreases, which means improve of quality of life for all domains, except general health domain, when compared both treated groups and CG after treatment. Regarding satisfaction reported, 14/15 (93.3%) of the VC group subjects and 12 of 13 (92,3%) of the PFMT group subjects showed that they were satisfied with treatment. There were no complaints of adverse effects due to treatment from either group.

Conclusions:
In conclusion, this study verified similar positive results for treatment with vaginal cones and pelvic floor muscle training for urinary loss, pelvic floor muscle pressure, quality of life and satisfaction, both treatments appear to be effective for treatment of SUI in this population.

References:
1. *The Cochrane Library*. 2009; DOI: 10.1002/14651858.CD002114.pub2.

Presentation Number: 056

REPEAT VERSUS PRIMARY SYNTHETIC SLING IN PATIENTS WITH INTRINSIC SPHINCTER DEFICIENCY

A. L. SMITH, D. KARP, V. C. AGUILAR, G. W. DAVILA;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To compare subjective and objective outcomes of repeat vs. primary synthetic slings in patients with stress urinary incontinence due to intrinsic sphincter deficiency (ISD)

Background:
Recurrent stress urinary incontinence (SUI) after synthetic sling is frustrating for both the patient and the surgeon. The failure rates for slings range from 5% to 15% with ISD patients having the highest risk of failure. Additionally, recent literature suggests that cure rates are lower following repeat synthetic slings compared to primary slings. However in many of these studies significantly more patients undergoing repeat sling had a diagnosis of ISD [1]. It was our goal to evaluate the outcomes of repeat sling in a cohort of patients with ISD.

Methods:
We reviewed all patients with a diagnosis of ISD who underwent anti-incontinence sling at our institution. Patients with a maximal urethral closure pressure ≤20 cm H2O, and/or Valsalva leak point pressure ≤60 mmHg were diagnosed with ISD. Patients were divided into two groups according to whether they were undergoing a primary sling or a repeat sling for recurrent SUI.

Data analyzed included demographics, subjective measures of incontinence severity, urodynamic parameters, and intraoperative characteristics including concomitant prolapse surgery and sling type. Postoperative data included self-assessment of cure, incontinence symptoms, standardized stress test results, and the need for re-intervention with urethral bulking agents any time during the postoperative course.

The primary outcome measure was cure as defined by lack of re-intervention for stress incontinence with a report of no stress or mixed incontinence at final follow up visit. Statistical analysis was performed using the unpaired t-test, Wilcoxon rank sums test, and Chi-squared/Fisher's exact to compare differences between the groups. Binary logistic regression was used to identify independent risk factors associated with failure.

Results:

Between 2003 and 2010, 637 patients with ISD underwent a suburethral sling at our institution. 557 patients (87%) had a primary sling and 80 patients (13%) a repeat sling. The groups were similar according to age, BMI, parity and menopausal status (Table 1). Preoperatively, patients with recurrent stress incontinence had significantly more subjective bother and more incontinence procedures (retropubic colposuspension or urethral bulking) (Table 1). In the repeat sling group, mean time between slings was 6 (1–25) years.

Mean follow up was 66.5 weeks (6–374). Based on the primary outcome, primary slings had an 81% cure rate compared to 55% cure for repeat slings ($p<0.0001$). Repeat sling patients were 3.4 times more likely to fail surgery compared to patients with primary slings [OR=3.43, 95%CI(2.1,5.6)]. Additionally repeat sling patients reported lower subjective rates of "cure", more incontinence episodes, greater pad usage and increased urgency symptoms (Table 2). 30% of the repeat sling group underwent further re-intervention with urethral bulking postoperatively compared to 8.6% in the primary sling group [OR=4.4, 95%CI (2.5,7.7)].

Among patients undergoing repeat sling, prior incontinence procedure, positive supine stress test, and transobturator sling were all independent risk factors for failure. In the repeat group, transobturator slings were 12 times more likely to fail compared with retropubic TVT [OR=16.1, 95%CI(3.1,82.6) vs. OR=3.5, 95%CI(1.4,8.9)]. Among the three types of slings placed (transobturator, TVT, or bladder neck), bladder neck slings resulted the highest cure rate [OR=2.7, 95%CI(1.4,5.2)].

Conclusions:

Repeat sling procedures are associated with lower objective and subjective success rates when compared to primary slings in women with ISD. Bladder neck slings result in the highest success when compared to both transobturator and retropubic slings.

TABLE 1: Patient characteristics

	Repeat n=80	Primary n=557	*p-value*
Age	65.9±9.8	68.1±12.1	*0.06*
BMI	26.9±4.8	27.4±5.1	*0.48*
PARITY	2 (0–6)	2 (0–12)	*0.21*
POSTMENOPAUSAL	69 (86)	472 (85)	*0.72*
PREVIOUS HYSTERECTOMY	54 (68)	245 (44)	***<0.001***
PREVIOUS INCONTINENCE PROCEDURE	12 (15)	42 (8)	***0.03***
CONCOMITANT PROLAPSE SURGERY	53 (66)	469 (84)	***<0.001***
SLING TYPE			
• Transobturator	9 (11)	123 (22)	***0.025***
• Retropubic (TVT)	22 (28)	152 (27)	*0.97*
• Bladder neck	49 (61)	282 (51)	*0.075*

*expressed as mean ± sd, median (range), and n (%) where appropriate

TABLE 2: Postoperative outcomes

	Repeat n=80	Primary n=557	*p-value*
CURE—No c/o SUI/MI & No bulking	44 (55)	453 (81)	***<0.0001***
RE-INTERVENTION	24 (30)	48 (9)	***<0.0001***
SELF-ASSESSMENT "CURE"	43 (54)	376 (68)	***0.015***
SUBJECTIVE URGENCY/MI	44 (55)	218 (39)	***0.007***
INCONTINENT EVENTS/DAY			
• 0 Inc/day - "Dry"	1.38±1.6 40 (50)	1.02±1.6 355 (64)	***0.02*** ***0.018***
PAD USAGE/DAY			
• 0 Pads/day - "Dry"	1.18±1.2 36 (45)	0.85±1.1 336 (60)	***0.01*** ***0.009***
POSITIVE EMPTY SUPINE STRESS TEST	4 (1.9)	8 (1.4)	***0.03***

*expressed as mean±sd, median (range), and n (%) where appropriate

References:

1. J UROL 2010; 183: 241–246.

Presentation Number: 057

6 YEARS FOLLOW-UP AFTER TVT AND TVT-O CONTINENCE PROCEDURES TO TREAT USI

P. PIFAROTTI[1], C. DELL'UTRI[1], D. CONSONNI[2], C. GARGASOLE[1], A. BUONAGUIDI[1], G. BOLIS[1];
[1]Dept. of Obstetrics and Gynaecology, Clinica "L. Mangiagalli", Univ. of Milan, Milan, Italy, [2]Epidemiology Unit, Ospedale Maggiore Policlinico, Milan, Italy.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To compare long-term effectiveness, complications and reoperation rates of two continence procedures in the treatment of urodynamic stress incontinence (USI): the retropubic route of tension free vaginal tape (TVT) with the trans-obturator inside-out tape(TVT-O).
Background:
Recently there is an increasing use of TVT-O because of its shorter operative time and lower perioperative risk than TVT. Both techniques appear to be equally effective, however these findings are limited by the heterogeneity of the outcome measures and by the short length of follow-up.
Methods:
Three-hundred and seventy-eight women diagnosed with USI and symptomatic for moderate to severe SI (according to Ingelman-Sundberg Score), who underwent two surgical continence procedures (178 TVT,176 TVT-O) were included in this retrospective observational study. Preoperatively the groups did not differ significantly in any of the characteristics investigated (age, parity, mode of delivery, BMI, menopausal age, pelvic organ prolapse). Preoperative and postoperative evaluation included an accurate interview, a frequency-volume chart, several validated questionnaires, the Visual Analogue Scale to assess the impact of USI on quality of life and a uro-gynaecological examination. Stress incontinence was objectified by a positive cough-test. Urodynamics was performed to evaluate lower urinary tract function preoperatively and the results where homogenous in the two groups for all the urodynamic-parameter observed. Exclusion criteria were: a previous continence surgery and/or concurrent surgery, previous radiation therapy of the pelvis, active malignancy, neurogenic diseases and lower urinary tract abnormalities. Mann–Whitney and Chi-Square tests were used to compare qualitative and categorical data between groups. Satistical significance was set at $p<0,05$.
Results:
Two hundred and fifty-eight patients (122 TVT, 136 TVT-O) out of 345 initially included were evaluated at a mean follow up period of 41,5 months (range 9–74). Mean operative time was significantly shorter in the TVT-O group (29,7 vs 18,0 min, $p<0.001$). No differences were found in terms of intraoperative blood loss, hospital stays and perioperative complications. Vaginal erosions were observed significantly more after TVT-O (9 vs 1,7%, $p=0.01$). Voiding difficulties and de novo urge-incontinence were slightly lower in TVT-O group, whereas groin pain was more common after TVT-O (p value>0,05). Because of the low occurrence rates of peri- and post-operative complications in both surgical treatments, the patient number was not big enough to detect reliable significant differences. Quality of life improved significantly in both groups after the treatment. Although long term objective cure rate was significantly higher in the TVT group (82,8 vs 71,3% $p<0,05$), the subjective effectiveness suggested equivalent results for TVT and TVT-O (81,1 and 72,0% respectively, $p=0,11$).The estimated risk ratio of failure was 1,72 times higher in the TVT-O group (IC 95%:1.03–2.85), $p<0,05$.
Conclusions:
TVT appears to be significantly more effective in the treatment of USI and to have a higher long-term durability than TVT-O. However, TVT-O seems to be correlated to a significantly lower rate of intra-operative complications; therefore high risk patients, those who are at such risk of morbidity might benefit from the trans-obturator approach rather than from the retropubic one. We suggest that risk assessment could be used as part of a standardization tool to allow comparison of outcomes between these surgical techniques in further studies.
References:
Neurourol Urodyn 2002 21:167–178; Prog Urol 2001;11:1306–13; Int Urogynecol J Pelvic Floor Dysfunct. 2007 Nov;18 (11):1257–61.

Presentation Number: 058
LONG TERM OUTCOME RESULTS OF THE INSIDE-OUT TRANSOBTURATOR TENSION FREE VAGINAL TAPE (TVT-O): EFFICACY AND RISK FACTORS FOR SURGICAL FAILURE
A. GROUTZ, R. GOLD, **D. GORDON**;
Lis Maternity Hosp., Tel Aviv, Israel.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The present study was conducted to assess the 5-year efficacy of the inside-out transobturator tension free vaginal tape (TVT-O) procedure and to explore possible predictors for long term failure.
Background:
Since first presented in 2003, several studies have confirmed the safety and short term efficacy of the TVT-O for the treatment of stress urinary incontinence (SUI). However, long term outcome results of the TVT-O procedure are scarcely available. To the best of our knowledge, to date, only one previously published study reported 5 years outcome results of TVT-O (1).
Methods:
65 consecutive patients who underwent TVT-O for urodynamic SUI were prospectively enrolled. Patients who required concomitant anterior and/or apical pelvic organ prolapse repair, and those with urodynamic occult SUI were excluded. Postoperatively, patients were scheduled for evaluation at 1, 3, 6 and 12 months, and annually thereafter. Urodynamic evaluation was routinely undertaken 3 months after surgery. The 5 years outcome results were assessed by pelvic examination with a full bladder, stress test (Valsalva maneuver), medical documentation of postoperative complications (such as recurrent UTIs, vaginal erosions), further treatments (pharmaceutical, surgical, or others), and focused questioning regarding the occurrence and severity of lower urinary tract symptoms. Patients were also asked what is their global satisfaction (cure, improvement, or failure), and whether or not they will recommend such a surgery to a friend with a similar problem. Surgical failure was defined as positive stress test, daily episodes of SUI, and negative ("failure") global satisfaction. Improvement was defined as infrequent episodes of SUI, and cure was defined as negative stress test, no episodes of SUI, and positive ("cure") global satisfaction. Preoperative and interim 1-year clinical and urodynamic predictors for long term surgical failure were analyzed from a computerized database.
Results:
61 patients (mean age at surgery: 56.6±10.2 years) completed 5 years follow-up. Of these, 11 (18%) patients were classified as surgical failure, 5 (8%) as improved, and 45 (74%) as cure. Of the various preoperative clinical and urodynamic characteristics of failure ($N=11$) versus cure/

improved (*N*=50) cases, preoperative concomitant overactive bladder-OAB (100% versus 66%, P=0.025) and urodynamic detrusor overactivity-DO (73% versus 28%, *P*=0.005) were found to be significantly more common among failure cases. Of these, only preoperative urodynamic DO (OR 7.6, 95% CI 1.7-32.9) was found to be significant independent risk factor for long term failure in the multivariate logistic regression model. Of the various interim (1 year) clinical and urodynamic parameters, OAB (91% versus 32%, *P*= 0.001), SUI (36% versus 2%, *P*=0.003), urodynamic SUI (55% versus 10%, *P*=0.003), and urodynamic DO (73% versus 16%, *P*=0.003) were found to be significantly more common among failure cases. Of these, only OAB (OR 20.5, 95% CI 1.9–215.4) and symptomatic SUI (OR 26.4, 95% CI 1.5–475.2) were found to be significant independent risk factors for long term failure in the multivariate logistic regression model. Five years clinical characteristics of the failure versus cure/ improved cases are presented in Table. Of the various parameters, any SUI, daily SUI, OAB, and the use of anti-muscarinic drugs were found to be significantly more common among failure cases.

Conclusions:

18% rate of surgical failure was observed 5 years after TVT-O. Larger studies with longer follow-up may facilitate the identification of risk factors for surgical failure and thus enable better preoperative consultation.

References:

1. Eur Urol 2010; 58:671–677.

TABLE: Five-years outcome results

Mean ± SD or N (%)	Failure *N*=11 (18%)	Cure/Improved *N*=50 (82%)
SUI (any frequency)	11 (100%)*	5 (10%)
SUI (daily)	11 (100%)*	0
OAB	11 (100%)*	24 (48%)
Anti-muscarinic drugs	7 (64%)*	13 (26%)
Recurrent UTIs	1 (9%)	7 (14%)
Additional SUI surgery	1	0

* *P*< 0.05

Presentation Number: 059

A PROSPECTIVE RANDOMISED CONTROLLED TRIAL COMPARING VAGINAL PROLAPSE REPAIR WITH AND WITHOUT TENSIONFREE VAGINAL TAPE TRANSOBTURATOR TAPE (TVTO) IN WOMEN WITH SEVERE GENITAL PROLAPSE AND OCCULT STRESS INCONTINENCE: LONG TERM FOLLOW UP

A. E. FUENTES;
Hosp. PEREZ CARREÑO, CARACAS, Venezuela, Bolivarian Republic of.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To compare the use of TVTo sling or not in the treatment of occult urinary stress incontinence (OSI) at the time of vaginal prolapse repair.

Background:

A prospective, randomized controlled trial was conducted of women with OSI defined as symptomatically continent women with urodynamic stress incontinence (USI) with (or without) reduction of prolapse (> Stage 3 on POPQ examination).

Methods:

A prospective, randomized controlled trial was conducted of women with OSI defined as symptomatically continent women with urodynamic stress incontinence (USI) with (or without) reduction of prolapse (> Stage 3 on POPQ examination).Ethics committee approval was obtained, the rules in the declaration of Helsinki were followed and informed consent was obtained prior to entry in the study. The pre- and 6 month post-operative, 12 months post - operative and 24 months post-operative, protocol included: complete urogynaecological history, physical examination, multi channel urodynamics testing, 1-h pad test and a 3 day bladder diary. The UDI 6 SF, IIQ7 SF, PISQ and visual analogue score (VAS) were used for subjective assessment of quality of life (QOL) and treatment success. Women were randomized to either prolapse surgery and TVTo or prolapse surgery alone. Prolapse repair was performed according to surgeon preference with Prolift system, with cleisis procedure or classical technique and according the preference of each patient if she want a reconstructive surgery or not . The primary endpoint assessment was the need for subsequent anti incontinence surgery. Follow up at 6 month has been previously reported and has been continued annually thereafter. Further women were recruited to the study to allow for the participants that were deceased, lost to follow up and withdrawn

Results:

From Feb 2008 to Dic 2010 sixty (60) women were enrolled with randomization of 33 to no sling (i.e. prolapse surgery alone) and 27 to TVTo and concurrent prolapse repair. No significant differences in demographic or clinical characteristics of either group were detected. The types of prolapse surgery was similar in the no TVTo and TVTo groups.(Table1) The median follow up [25th–75th percentile] was 20 months . The primary endpoint was the clinical need for stress incontinence surgery postoperatively. 6 (18.1%) TVT0 slings were inserted in the group of women with prolapse surgery and no sling procedure; and 1 TVT in the prolapse and TVTo group. The time from prolapse repair to sling insertion in the group of women with prolapse surgery alone was 1.4, 7, 9 and 15 months. The difference in times of sling insertion was tested using the log-rank test for equality of survivor function, *p*=0.08. Post operative complications such as haemorrhage, bladder perforation, and voiding difficulty specific to insertion of TVTo at the time of prolapse repair were already presented. The 6 month postoperative urodynamic assessment demonstrated USI in 6 (18.1%) of the non TVTo and one (3.7%) of the TVTo group This patient have a severe Esfinter intrinsic deficiency . In the non TVT0 group 6/33 women (18.1%) had bothersome objective USI requesting a TVT0 insertion. 27 of 33 women (81.8%) with USI remained asymptomatic and 26/27 (96.2%) women with occult USI in the TVT0 group had no USI on repeat urodynamic testing following vaginal repair of the prolapse and TVTo insertion. The remaining 8/33 (24.2%) not sling group declined repeat urodynamic assessment at 6 month.

Conclusions:

These results indicate that in women with occult SI and prolapse a clinician would have to insert 6 TVTo slings to prevent one woman needing a sling postoperatively. A correlation is noted between USI and subjective SUI as demonstrated by the 18.1% of women who don't remained asymptomatic postoperatively. This may be due to the

high sensitivity of the urodynamic testing demonstrating leakage at capacity of 400–500 ml. There is difference in QOL between the two groups demonstrated, as the number of symptomatic women requiring further surgery was important. The long term results (median follow up of 20 months) confirm the trend reported on previously at 6 months. Prolapse surgery without TVT0 cured occult USI at 6 month repeat testing in at least 8/33 patients. Furthermore 27 women in the non TVTo group, who were asymptomatic, did not require any further surgical intervention in the long term.

At greater than 2 years following pelvic organ prolapse surgery, these results indicate that the routine insertion of a mid-urethral sling, TVTo, in women with occult stress urinary incontinence and prolapse is recommendable because its too high return to operating room in 18.1% of times that the surgeon don't insert a mid-urethral sling. Women should be counselled regarding the possibility of stress urinary incontinence postoperatively. Longer term follow up will be continued.

Presentation Number: 060

WHICH SINGLE INCISION MID URETHRAL SLING SHOULD YOU USE? AN AUDIT OF TVT SECUR AND BARD AJUST WITHIN A SINGLE UNIT COMPARED TO THE BSUG UK DATABASE

R. ASSASSA[1], Z. GIRN[2], A. THANGAVELU[1], P. MORAN[3], B. BSUG COMMITEE[4];

[1]Mid Yorkshire NHS Trust, Pontefract, United Kingdom, [2]Harrogate NHS Trust, Harrogate, United Kingdom, [3]Worcester NHS Trust, Worcester, United Kingdom, [4]British Society of Urogynaecology, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To audit the results of single incision mid urethral slings (MUS), within our unit, against the British Society of Urogynaecology (BSUG) surgical database for retropubic MUS (used as comparative standard)

Background:
Single incision mid urethral slings (MUS) are becoming more widely used as they may be associated with low intra-operative morbidity, the opportunity to be performed under local anaesthetic and low post-operative pain. The results of Single incision MUS are however less well established and units must audit their own results to show local success rates.

Methods:
We have performed 245 primary operations on women with USI or mixed incontinence, without concomitant surgery, and entered their data on the BSUG database. 142 were TVT Secur (Gynaecare) and 103 were Ajust (Bard). Complications were recorded as per the BSUG database. All patients filled in an ICIQ-LUTSqol questionnaire (score 19–76) and 3 day urinary diary before and after surgery together with an improvement scale for both stress incontinence and urgency/urge incontinence. We have compared these results against the BSUG national data for similar cases undergoing retro pubic MUS.

Results:
All patients were admitted as day cases and went home the same day.

	Secur n=142	Ajust n=103	Retropubic MUS (BSUG National Data n=3990)
Age	54 (range 30–85)	51 (range 32–85)	53 (range 11–100)
Urodynamic Diagnosis	USI 84 (60%) Mixed 58	USI 53 (51%) Mixed 50	USI 73%
Anaesthetic n (%)			
GA	71 (50%)	23 (22%)	65%
Spinal	5 (4%)	1 (1%)	15%
LA with sedation	0	2 (2%)	19%
Local alone	66 (46%)	77 (75%)	1%
Bladder injury	0	0	2.9%
Major intra-operative complication	0	0	0.6%
Catheterised >10 days	0	0	2.1%
ICIQ-LUTS Score Pre-post	50–29	53–27	51–28
Change in stress incontinence			
Cured	97 (74%)	72(97%)	73%
Improved	23 (17%)	2 (3%)	20%
No Change	10 (8%)	0	6%
Worse	1 (1%)	0	1%
Change in Urgency/urge incontinence			
Cured/not present	66 (64%)	39 (53%)	54%
Improved	15 (15%)	10 (14%)	22%
No Change	11 (11%)	13 (18%)	15%
Worse	7 (7%)	5 (7%)	5%
New Symptom	4 (4%)	6 (8%)	4%

Conclusions:
Single incision MUS compare favourably with retropubic MUS in that they are easily performed under pure local anaesthetic with minimal intra-operative complications and result in significant improvement in QOL. The Ajust had a higher success rate for subjective stress incontinence in our unit than the TVT Secur. This may be a consequence of a stronger fixation mechanism or the ability to adjust the tape dynamically and individually for each patient.
There is now a need to perform a randomised controlled trial assessing the best single incision MUS against standard MUS.

References:
Assassa et al. Stress incontinence in the UK (1). Pre-operative work up and intra-operative complications IUGA/ICS 2010
Assassa et al. Stress incontinence in the UK (2). Post surgery success, follow-up and complications. IUGA/ICS 2010

Presentation Number: 061

RANDOMISED TRIAL OF TVT-O AND TVT-S FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

A. H. BIANCHI, Z. I. JARMY-DI BELLA, R. A. CASTRO, M. G. SARTORI, M. J. GIRAO;
UNIFESP (Federal Univ. of São Paulo - Brazil), São Paulo, Brazil.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objective:
The objective of this study is to compare the efficacy and complications of TVT-O and TVT-S midurethral tapes as surgical treatment for stress urinary incontinence.

Background:
Single incision slings were developed to reduce complications of retropubic and transobturator approaches, nevertheless there are still few studies about efficacy and complications of these thecnics.

Methods:
This is an ongoing prospective randomized study. Women with urinary stress incontinence, without detrusor overactivity and no concomitant prolapse stage ≥ 2 (POP-Q) were elligible.
All patients underwent pre-operatory clinical evaluation with pad-test and urodynamic test. Quality of life was also evaluated through the King's Health Questionnarie (KHQ). After signing an informed consent patients were randomized to have either TVT-O™ (56) or TVT-Secur™ (66) procedure.
The procedures were performed either under local anaesthesia and sedation or raquianesthesia according to published techniques. Clinical evaluation, pad-test and the KHQ were again performed 30, 90, 180 days 1 and 2 years after the procedure. Urodynamic test was again performed 6 months and 1 year after the procedure. Statistical analysis were performed by using Statistical Package for Social Sciences (SPSS v18.0). Statistical significance reached when $p<0.05$.

Results:
The two groups are similar regarding to demographic and clinical pre-operatory parameters (table 1) Continuous variables are expressed in mean ± standard deviation.

Table 1. Pre-operatory data

	TVT-O	TVT-S	p
Number of patient	56	66	
Age (y)	52,13 (±8,79)	54,05 (±11,37)	0,305
BMI (kg/m^2)	30,02 (±4,69)	29,84 (±5,35)	0,847
Parity	3,64 (±2,26)	4,05 (±2,65)	0,302
Mean value pre-op pad-test (g)	19,87 (±25,39)	19,9 (±22,85)	0,909
Mean value pre-op VLPP (cm H2O)	85,34 (±36,43)	79,39(±27,7)	0,404

T Student, Qui^2,Mann–Whitney

Table 2. Post Operatory results

	TVT-O	TVT-S	p
Number of patients	56	66	
Mean Follow up (m)	18 (6–24)	18(6–24)	
Continent patient (subjective)	53 (94,6%)	37 (92,5%)	1,00
Objective cured (Negative post -op pad test and negative VLPP)	51 (91,7%)	60(90,9%)	1,00

Fisher

Table 3. Post-Operatoty complications

	TVT-O	TVT-S	p
Number of patients	56	66	
Mean Follow up (m)	18 (6–20)	18 (6–20)	
Urinary retention	2 (3,5%)	2 (3,0%)	1,00
Urinary infection	4 (7,1%)	3 (4,5%)	0,702
Tight pain	15 (26,7%)	1 (1,5%)	<0,001
Tape exposure	1 (2,7%)	1 (2,5%)	1,00

Fisher

Conclusions:
We have observed that both techniques have had similar results in 18 months mean post operatory follow-up .The two groups have had similar subjective and objective continence rates, without statistical difference (table 2). Only minor complications (table 3) have been observed: urinary retention up to 5 days, uncomplicated urinary infection, tight pain up to 10 days and 1 patient in each group have had assintomatic tape exposure. Only 1 patient had de novo urgency.This study is still underway in order to have a great number of subjects and a longer follow-up.

Presentation Number: 062

IS MINIARC A STANDARDIZED PROCEDURE? A 3D ULTRASOUND STUDY

F. SPELZINI[1], M. CESANA[2], M. SICURI[1], R. MILANI[1];
[1]Ginecologia Chirurgica, Ospedale San Gerardo, Monza, Italy, [2]Università Milano Bicocca, Monza, Italy.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
Aim of this study is to correlate MiniArc® cure rate to sling position assessed with pelvic floor 3D ultrasound.
Background:
MiniArc® (MA) is a single incision device for the treatment of stress urinary incontinence. It is based on a self-fixating suburethral tape bilaterally anchored in the obturator internus muscle as suggested by the manufacturer. It is common opinion among frequent and occasional users of MA that the position of the self-fixating tips is variable and sometimes not symmetrical. As consequence of a different bony pelvis width, fixation site may vary according to ischio-pubic branches distance. Moreover urethral position can be influenced by a mild degree of anterior compartment descent. In other words patient's anatomy requires extemporary adjustments of the technique in order to assure a proper tension of the sling. The tips can reach and cross the obturator membrane, stop in the oburator internus muscle or lay in the retro-obturator connective tissue. Polypropylene tape is detectable at ultrasound examination, thus the position of the tape and the intergated tips can be assessed with a combined 2D-3D ultrasonographic approach.
Methods:
All the patients surgically treated for isolated stress urinary incontinence with MA between January 2009 and September 2010 were included in this observational study. Recruited patients underwent ultrasound examination between November and December 2010. A perineal scan was performed using a BK Pro Focus 2202® machine. Each perineal ultrasonography included a 2D translabial sagittal evaluation to assess bladder neck and tape mobility at rest and during maximal straining. A 3D transvaginal evaluation of the anterior compartment was obtained using the linear array of 8848® probe. From each volume was possible to assess the tape position along the urethral axis and the position of self-fixating tips was bilaterally checked: the presence of a gap between tips and the ischiopubic branches was considered and indirect sign that the obturator membrane was not reached. According to this principle we divided the patients in group A (both tips crossed the membrane), group B (only one tip crossed the membrane) and group C (none of the tips crossed the membrane). Each group was correlated with tape and bladder neck mobility. All parameters (bladder neck mobility, tape mobility and position, tape anchorage) were then compared to the objective cure rate (negative stress test at urodynamics). Any difference was considered statistically significant when p value calculated with Student's t test was <0.05.
Results:
79 patients underwent MA procedure during study period. A complete evaluation was completed in 57 patients with a mean follow up of 11 months. Objective cure rate (negative stress test) was 87,7%. 13 patients were assigned to group A, 23 to group B and 21 to group C. A significant (p=0.01) difference in tape mobility was noted between group A (median=2.3 mm) and group C (median=5 mm). Both tape and bladder neck mobility (median =2.49 mm and 4.3 mm, respectively) increased in failures, with a significant difference (p=0.05) only in bladder neck position. Sling was significantly (p=0.03) closer to middle urethra in cured patients (median distance=4 mm, corresponding to 9% of urethral length) than in failures (median distance=7.1 mm corresponding to 18% of urethral length).
Conclusions:
In 77% of patients MA didn't reach the obturator membrane on both sides. This feature conditioned significantly tape mobility. Tape and bladder neck mobility were both involved in the effectiveness of the procedure but only bladder neck mobility was significantly correlated. Tape position along the urethral axis also influenced the efficacy of the procedure. A dislocation of more than 10% of total urethral length from the middle urethra seems to be associated with higher risk of failure. In conclusion in this study the overall objective cure rate of MiniArc® was high, but the procedure is not standardized and surgeon's subjective sensitivity plays a role. Pelvic floor ultrasound confirmed to be a valid tool in the assessment of functional anatomy.

Presentation Number: 063
CURRENT PRACTICE IN THE UK FOR THE ASSESSMENT AND MANAGEMENT OF RECURRENT STRESS URINARY INCONTINENCE IN WOMEN
M. RIAD, A. FAMILUSI, M. EL SAYAD, M. ABDEL-FATTAH; Univ. of Aberdeen, Aberdeen, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To assess the current practice for the management of recurrent Stress Urinary Incontinence (SUI) after failed continence surgery through a national survey comparing potentially different practice of generalist gynaecologists (GG) versus urogynaecologists (UG) in the UK.
Background:
Recurrent SUI is an increasingly common and complex problem and failure rates has been reported to be up to 37% for mid-urethral slings (MUS),[1] The assessment and management of recurrent SUI represents a dilemma for most specialists as the evidence in the literature is deemed to be scarce and of low quality. The choice of the second procedure is important as it has been shown that success rate decreases proportionally to the number of subsequent operations performed.
Methods:
A questionnaire was designed in relation to the assessment and management of recurrent SUI in women. Surgeons were asked about their initial management, which investigation they would choose prior to surgery and how would the urodynamics (UDS) results influence management. Furthermore, they were asked about the secondary continence procedure of their choice according to the type of previous failed surgery.
The questionnaire was sent nationally to GG (n=400) and UG (n=200) practicing in the UK after obtaining relevant membership contact lists and approvals from the Royal College of Obstetricians & Gynaecologists (RCOG) and British Society of Urogynaecologists (BSUG) respectively.
Results:
162 questionnaires were returned as incorrect addresses and 289/438 replies were received (response rate: 66%). Sixty-

three (63) declared they don't deal with urogynaecology cases; leaving 226 responses for analysis (GG n=115 Vs UG n=111).

149 surgeons (81.9%) agreed that recurrent SUI represents a dilemma to their clinical management. Once recurrent UI is diagnosed/suspected by history taking; 77% of surgeons (n=156) would recommend pelvic floor muscle training (PFMT) prior to surgery or having UDS regardless whether it has been done before primary surgery or not.

If secondary surgery is contemplated, the majority of surgeons agreed that urinary diary (95.8%), free uroflowmetry (94.2%), multichannel subtraction filling cystometry (99.5%), and voiding cystometry (98%) should be one of the tools for assessment before surgery. However, only 89 (55.6%) agreed that Urethral Pressure Profilometry (UPP) should be done before surgery, with more agreement from GG (53; 65.4%) versus UG (36; 45.6%), (P 0.018).

More UG (103; 99%) than GG (91; 89.2%) agreed that free Uroflowmetry is a necessary diagnostic tool prior to surgery (P 0.007).

(Table 1) Management of recurrent SUI agreed by clinicians according to UDS results

	Whole cohort n (%)	Gynaecologist n (%)	Gynaecologist n (%)	*P* value
If USI is NOT confirmed on UDS, I proceed to				
1. Ambulatory UDS	79 (58.5)	39 (55.7)	40 (61.5)	0.609
2. Video UDS	83 (65.9)	34 (59.6)	49 (71)	0.25
3. Pad test	90 (68.7)	40 (66.7)	50 (70.4)	0.785
4. Repeat conservative management	101 (69.7)	52 (70.3)	49 (69)	1
If Mixed UI is diagnosed in UDS				
1. Perform surgery if recurrent USI is the bothering symptom	124 (64.6)	59 (61.5)	65 (67.7)	0.451
2. Control OAB symptoms prior to surgery	173 (88.3)	84 (87.5)	89 (89)	0.917
If USI is confirmed on UDS				
1. Repeat PFMT if not done prior to surgery	151 (78.2)	80 (80.8)	71(75.5)	0.476
2. Choice of secondary surgery depends on the type of primary operation	182 (91)	99 (95.2)	83 (86.5)	0.056

If surgery is required, surgeons have chosen the secondary continence surgery according to the type of primary failed surgery. Results are illustrated in table 2.

(Table 2) Recommended secondary surgery for recurrent SUI by clinicians according to type of primary surgery

Failed primary surgery	Chosen Secondary surgery	Number of clinicians n (%)	Agree Gynaecologist n (%)	Agree Gynaecologist n (%)	*P* value
Colposuspension	Retropubic TVT	147 (87.5)	67(85.9)	80 (88.9)	0.726
	TOT	142 (83)	74 (87.1)	68 (79.1)	0.235
Retropubic TVT	TOT	119 (74.8)	58 (75.3)	61 (74.4)	1
	Bulking agent	103 (71.5)	48 (69.6)	55 (73.3)	0.752
	Repeat TVT	91 (61.9)	29 (44.6)	62 (75.6)	<0.005
TOT	Retropubic TVT	145 (91.2)	58 (85.3)	87 (95.6)	0.047
Previous failed 2 continence procedures	Bulking agent	114 (80.9)	55 (80.9)	59 (80.8)	1
	Rectus fascial sling	59 (50.9)	20 (39.2)	39 (60)	0.042
	Retropubic TVT	50 (45.5)	18 (34.6)	32 (55.2)	0.049

Most of surgeons agreed that women with recurrent SUI should be managed by a subspecialist 145 of 194 (74.7%), and most of them believe that primary and secondary research projects are needed.

Interpretation of results:

Despite evidence that Intrinsic Sphincteric Deficiency (ISD) is associated with low success rates and risk of recurrence, [2] only just above half of surgeons (55.6%) mostly GG (65.4%) recommended UPP. In addition, despite some evidence that TVT has better outcome in patients with recurrent SUI, [3] most UK surgeons have selected the TOT as the secondary procedure of choice after failed colposuspension (83%) or TVT (74.8%). Significantly, there were more UG than GG agreed for retropubic TVT as a secondary procedure after failed retropubic TVT (P<0.005), TOT (P 0.047), and previous failed 2 continence procedures (P 0.049).

Conclusion:

This survey has shown the significant variation among UK GG & UG in their diagnosis & management of women with failed continence surgery, however the majority would recommend

repeat PFMT, undertake some form of urodynamic investigations and the type of repeat surgery would depend on the type of previously failed surgery with transobturator tapes as the most commonly performed. Most surgeons (81.9%) declared that their choices are not evidence-based and believe that high quality primary research is required in this area which has a clear gap in the literature.

Reference:
1.Minim Inv Gynecol 2008; 15:132–145. 2.J Urol 2004; 172:1370–3.
3.Obstet Gynecol 2008; 112:1253–61.

Presentation Number: 064

DOES CHILDBIRTH ALTER THE REFLEX PELVIC FLOOR RESPONSE TO SUDDEN INCREASES IN INTRA-ABDOMINAL PRESSURE?

V. BOND, S. E. LANGER, K. SHEK, **H. DIETZ**;
Univ. of Sydney, Penrith, Australia.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To examine whether childbirth results in an alteration of reflex pelvic floor activity on coughing.

Background:
SUI has long been supposed to be due to abnormal support of the bladder neck and/or mid-urethra. The quality of the urethral sphincter clearly also plays a role. However, urethral mobility and urethral closure pressure explain only a small part of the variability of stress continence. Altered reflex activation of muscular pelvic floor structures, which can be detected by translabial ultrasound (US), may also contribute.

Methods:
131 nulliparous women at a mean gestation of 35.8 (33–37) weeks were recruited from antenatal clinic. They were invited for a 2nd assessment at least 3 months postpartum, consisting of an interview and 4D translabial US. Volume US data was obtained at rest, on maximal Valsalva and pelvic floor muscle contraction, and at least one cough was registered at a minimum of 16 Hz, using a 10-15 deg acquisition angle. All data was saved for later analysis using postprocessing software, blinded against all other data. To quantify a reflex contraction of the levator ani we measured the midsagittal hiatal diameter at rest, on maximum cough, on maximum reflex levator contraction and after the cough. We determined the timing of the contraction relative to maximum bladder neck displacement. We rated a reflex contraction as present if there was a reduction in hiatal diameter just prior to or during coughing. Levator integrity was determined using tomographic US. This prospective study was approved by the local IRB.

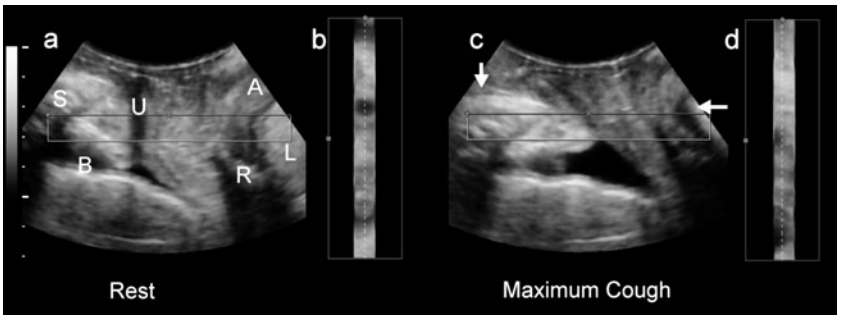


Figure 1: Activation of external perineal muscles displaces the clitoris (vertical arrow), and activation of the levator ani accentuates the anorectal angle (horizontal arrow). S = symphysis pubis, B = bladder, U = urethra, R = rectum, A = anal canal, L = levator ani. The vertical strip- like images (b,d) show the axial plane in a narrow rendered volume.

Results:
A test- retest series (n=58) on midsagittal measurements yielded an ICC of 0.93 (0.89–0.96). Of 131 women who had both antepartum and postpartum coughs registered, 47 were technically suboptimal, leaving 84. All subsequent data refers to this dataset. Mean age was 29.6 (19.5–42.3) years. BMI was on average 23.7 (16.9–47.2). Patients were seen at a gestation of 35.8 weeks (33.6–37.4) and 4.6 months (2.3–9.7) postpartum. Delivery data are shown in Table 1. 26 women complained about stress incontinence at the antepartum visit, and 20 women reported SI at the postnatal visit. Levator defects were diagnosed on tomographic US in 6 women (9.4% of vaginally delivered patients).

Table 1: Obstetric data (n=84)

Parameter	Mean or median	n (%)	Range
Normal vaginal delivery (n,%)		46 (55%)	
Vacuum extraction		15 (18%)	
Forceps delivery		3 (4%)	
Prelabor caesarian section		2 (2%)	

Caesarean section in 1st stage		12 (14%)	
Caesarean section in 2nd stage		6 (7%)	
Length of first stage (min)	410		33–1209
Length of second stage (min)	61		5–231
Birth weight (g)	3434		2615–4455

Antenatally, we documented a pelvic floor reflex in 82/84 women (98%). At the postpartum appointment this was reduced to 63/84, ie., 75% ($P<0.001$). The difference in midsagittal diameter between rest and maximum contraction was 4.8 mm on average (0–17.1, SD 4.8 mm). After childbirth, this was reduced to 2.0 mm ($P<0.001$). Delivery mode was associated with a more marked reduction in reflex magnitude (P=0.042 on ANOVA). Length of 2nd stage, birthweight, head circumference, epidural pain relief and levator trauma were not shown to be confounders. There was a trend towards an association between reflex magnitude and postpartum SI (0.87 [SD 3.18] vs. 2.36 [3.5], $P=0.08$), but the timing of a levator reflex relative to a cough did not seem to play a role.

Conclusions:

Pelvic floor reflexes are altered by childbirth, especially by vaginal delivery. Their magnitude may be associated with postpartum urinary stress incontinence. The clinical significance of this finding is uncertain.

References:

1. Ultrasound Obstet Gynecol 2010;36:507–11.
2. Ultrasound Obstet Gynecol. 2010;36 ((S1)):129.
3. Am J Obstet Gynecol 2010;202:321–34.

Presentation Number: 065

IS PREGNANCY AND CHILDBIRTH GOOD FOR PELVIC FLOOR MUSCLE STRENGTH?

K. ELENSKAIA, A. H. SULTAN, R. THAKAR, I. SCHEER, R. SRIVASTAVA;
Croydon Univ. Hosp., London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To prospectively establish the effect of pregnancy and childbirth on pelvic floor muscle strength (PFMS).

Background:

Although many studies have been published on anatomical and functional changes of the pelvic floor following delivery (1,2) no study has prospectively evaluated PFMS using validated tools from the early antenatal period to 1 year postpartum. The effect of the pregnancy and/or the mode of delivery to PFMS are unclear.

Methods:

Pregnant women over 18 years of age with a singleton uncomplicated pregnancy were interviewed at 20 weeks (Visit 1) and 36 weeks (Visit 2). The pelvic floor muscle strength was measured at Visit 1, Visit 2, Visit 3 (14 weeks postpartum) and Visit 4 (12 months postpartum) using a perineometer (Elite 4, Genesis) positioning the mid balloon 3.5 cm proximal to the hymen (3). The maximum resting pressure (MRP) was recorded and then the maximum of three voluntary pelvic floor contractions was regarded as the maximum squeeze pressure (MSP). Change in muscle strength between Visit 1 and 4 was recorded as ΔMRP and ΔMSP. Each woman was asked about regularity of pelvic floor exercises (PFE) ("Do you perform PFE regularly?") and was then allocated to one of three exercise groups: those who gave a negative answer at both antenatal visits; those who responded positively at least once of the two antenatal visits and those who responded positively on both occasions. Normally distributed variables were analysed using parametric tests (multiple regression, ANOVA, t-tests). Non-normally distributed variables were analysed using non-parametric tests (Mann–Whitney, Kruskal-Walis, Wilcoxon).
Ethical approval (REC No 05/Q0806/9) and written informed consent was obtained.

Results:

403 women attended Visit 1 (182 nulliparous and 221 multiparous women) and 333 (83%), 278 (69%), 177 (44%) attended Visits 2, 3 and 4 respectively. 294 (73%) delivered vaginally and 92 (23%) by caesarean section. MRP and MSP improved significantly ($p=.000$), during pregnancy (Fig. 1) irrespective of whether they were performing pelvic floor exercises (PFE) or not ($p=.001$) (Fig. 2). Fourteen weeks after delivery (Visit 3), the perineometry findings reduced significantly compared to both antepartum measurements ($p=.000$). There were no significant differences in all measurements between Visits 1 and 4 ($p=.352$). There was no significant effect of mode of delivery ($p=.516$ and $p=.138$) and parity ($p=.994$ and $p=.314$) on ΔMRP and ΔMSP respectively.

Conclusions:

There appears to be a physiological increment in PFMS during pregnancy. The pelvic floor weakens temporarily after childbirth but recovers completely by 1 year. This recovery is not dependent on the mode of delivery. In terms of PFMS, any unsupervised PFE is better than no PFE. This information may be helpful during counselling of women who request elective caesarean section based on the assumption that vaginal delivery is associated with permanent pelvic floor weakness.

References:

1. Obstet Gynecol 101(1):46–53
2. BJOG 101(1):22–8
3. PhysTher 85(3):269–82

Presentation Number: 066

DO WOMEN NOTICE THE EFFECT OF CHILDBIRTH- RELATED PELVIC FLOOR TRAUMA?

H. DIETZ, S. E. LANGER, K. SHEK;
Univ. of Sydney, Penrith, Australia.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To determine whether women notice changes in pelvic floor function after childbirth, and whether such changes are associated with pelvic floor trauma.

Background:
In 10–30% of women, vaginal birth results in levator ani tears which are associated with pelvic organ prolapse. It is not clear whether women notice such changes.
Methods:
This is a retrospective analysis of two perinatal imaging studies. Patients were followed up 3–6 months postpartum. They were asked to estimate pelvic floor muscle strength. Translabial 4D ultrasound (US) was performed to assess the levator ani muscle. Imaging analysis was performed offline, blinded against all clinical data. The diagnosis of avulsion was made on tomographic US (TUI) if all three central slices, i.e., the plane of minimal dimensions, as well as slices 2.5 and 5 mm cranial to this plane, showed an abnormal insertion (3). Levator microtrauma was defined as an increase of 20% or more in hiatal area on Valsalva after childbirth. Both parent studies had been approved by the local IRB.

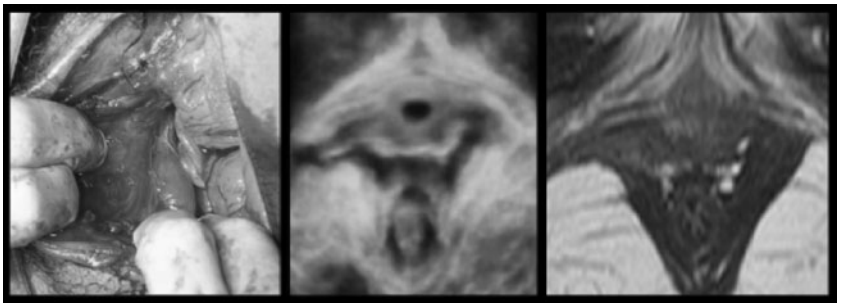


Fig. 1: Left-sided avulsion 3 months after NVD seen on rendered volume (US), magnetic resonance imaging (MRI) and tomographic US (TUI).

Results:
513 primiparous women were seen for follow-up in two prospective trials, at a median of 129 (IQR, 113–161) days postpartum. They had given birth to a singleton at a mean gestation of 40.0 (range, 36+0 to 42+5). There were 351 vaginal deliveries (27 Forceps, 60 Vacuum and 264 NVD) and 162 Caesareans (31.6%), of which 37 were performed before onset of labour, 91 in 1st stage, and 34 in 2nd stage. Mean birthweight was 3484 g (2010–4850 g). 98 (28%) had an episiotomy, 98 a 2nd degree, 21 (6%) a 3rd or 4th degree perineal tear.
At follow-up, 123 women complained of stress urinary incontinence SUI), and 22 of symptoms of prolapse. 482 were able to rate their pelvic floor strength relative to the situation prior to childbirth, reporting an average strength of 89.1%. This reduction was associated with delivery mode ($P<0.001$), length of 2nd stage ($P=0.017$), episiotomy ($P=0.019$) and marginally with perineal tears ($P=0.055$ on ANOVA). The greater the reduction in strength, the higher the likelihood of SUI ($P<0.001$) and, marginally, of symptoms of prolapse ($P=0.056$).
45 women were diagnosed with levator avulsion on TUI (36 r, 24 l, and 15 bilateral), 131 women with irreversible hiatal overdistension. The latter was not associated with subjectively reduced pelvic floor strength, but avulsion did result in a greater reduction (no avulsion, 89.6% vs, unilateral avulsion, 86%, bilateral avulsion 79.7%, $P=0.007$ on ANOVA), see Fig.2.

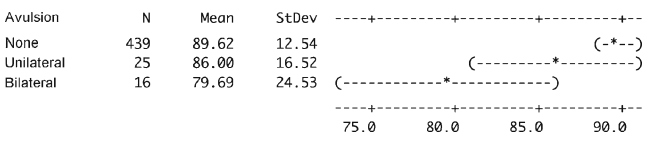


Fig. 2: Reduction in subjective strength and avulsion (P= 0.007 on ANOVA).

Conclusions:
Many women notice altered pelvic floor function after childbirth. Such changes are associated with postpartum symptoms of SUI. Vaginal childbirth, episiotomy, perineal tears and length of 2nd stage are associated with subjectively reduced pelvic floor strength after first delivery. Women who have suffered an avulsion notice a greater reduction in strength.
References:
1. FMMR. 2009;20:49–66.
2. Int Urogynecol J. 2008;19(5):633–6.
3. BJOG. 2010;117:1485–92.

Presentation Number: 067

A MEDIOLATERAL EPISIOTOMY DURING ASSISTED INSTRUMENTAL VAGINAL DELIVERY IS ASSOCIATED WITH A FIVE FOLD DECREASE OF A THIRD OR FOURTH DEGREE PERINEAL TEAR

J. DE VOGEL[1], A. VAN DER LEEUW- VAN BEEK[2], D. GIETELINK[1], M. VUJKOVIC[2], D. PAPATSONIS[1];
[1]Amphia Hosp., Breda, Netherlands, [2]Erasmus MC, Rotterdam, Netherlands.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To evaluate the incidence of a third or fourth degree perineal tear in women undergoing an assisted instrumental vaginal delivery, and to assess in these women whether a mediolateral episiotomy is preventive for developing a third or fourth degree perineal tear.

Background:
It has been proven that an assisted instrumental vaginal delivery is associated with an increased risk of a third or fourth degree perineal tear.(1),(2) It remains unclear if structural use of a mediolateral episiotomy during an assisted instrumental vaginal delivery will decrease the risk of a third or fourth degree perineal tear.
Methods:
A retrospective cohort study was performed between 2001 and 2009, using data from the clinical obstetric-database of the Amphia Hospital, Breda, The Netherlands. We selected all patients with live born infants beyond a gestational age of 34 weeks and delivered by an assisted instrumental vaginal delivery. Exclusion criteria were: multiple gestations, breech deliveries, congenital anomalies, and the use of a median episiotomy. The outcome measure was a third or fourth degree perineal tear. Continuous variables were compared using the Student's *t* test or the non-parametric Mann–Whitney *U* test. The $\chi 2$ test was used for categorical variables. Continuous variables were summarized as means with standard deviations, or medians with interquartile ranges (IQR). A logistic regression model was used for the risk assessment of the use of a mediolateral episiotomy on the risk for developing a third of fourth degree perineal tear. Treatment effect was presented as odds ratio with 95% confidence interval (CI).
Results:
The baseline characteristics of the two groups are shown in table 1. Patients in the group with a mediolateral episiotomy (MLE +) were younger (33.7 vs. 35.8, $P<0.001$), used more epidural anesthetics (20.6% vs. 11.8%, $P<0.001$) and had more blood loss (516 ml vs. 409 ml, $P<0.001$) compared to the group without a mediolateral episiotomy (MLE -). In the group without a mediolateral episiotomy were more primipara (27.3% vs. 12.3%, $P<0.001$), and more occiput anterior position (88.2% vs. 82.1%, $P<0.001$) compared to the group with a mediolateral episiotomy. $P<0.05$ was considered statistical significant. There were 2970 assisted instrumental vaginal deliveries performed who met the criteria. The incidence of a third or fourth degree perineal tear was 5.7% ($n=168/2970$). In the group patients with a mediolateral episiotomy the risk of a third or fourth degree perineal tear was 3.3% ($n=80/2403$), compared to 15.5% ($n=88/567$) in the group without a mediolateral episiotomy, OR 0.19 (95% CI: 0.14-0.26). After correction was made for gestational age at birth, parity, birth weight, maternal age, use of epidural analgesia, indication for instrumental delivery, cephalic fetal position, and duration of the second stage the risk estimate remains the same, OR 0.20 (95% CI: 0.12–0.34).
Conclusions:
The use of a mediolateral episiotomy in women undergoing an assisted instrumental vaginal delivery is associated with a statistical significant five fold decreased risk of developing a third or fourth degree perineal tear. Therefore we advocate the structural use of a mediolateral episiotomy during an assisted instrumental vaginal delivery, instead of selective use of a mediolateral episiotomy in order to prevent a third or fourth degree perineal tear.
References:
(1) Factors associated with anal sphincter laceration in 40,923 primiparous women. Int Urogynecol J Pelvic Floor Dysfunct 2007; 18:985.
(2) Risk factors for anal sphincter tear during vaginal delivery. Obstet Gynecol 2007; 109:29.

Table 1. Baseline characteristics

	MLE+*($n=2403$)	MLE - ^ ($n=567$)	P
Maternal age (years), mean±sd	33,7±4,8	35,8±5,4	<0,001
Primipara, n (%)	296 (12,3%)	155 (27,3%)	<0,001
Gestational age (days), median (p25–p75)	282 (274–288)	282 (275–288)	0,319
Usage of epidural anesthetics, n (%)	494 (20,6%)	67 (11,8%)	<0,001
Occiput anterior position, n (%)	1973 (82,1%)	500 (88,2%)	<0,001
Indication for instrumental delivery (= fetal distress), n (%)	636 (26,5%)	163 (28,7%)	0,271
Duration second stage (minutes), median (p25–p75)	70 (41–90)	55 (25–83,75)	0,13
Daytime obstetrics, n (%)	988 (41,1%)	232 (40,9%)	0,931
Male, n (%)	1331 (55,4%)	324 (57,1%)	0,450
Birth weight (grams), mean ± sd	3467±488	3409±552	0,955
Blood loss (ml), mean ± sd	516±498	409±336	<0,001

*MLE+: with mediolateral episiotomy.
^MLE-: without mediolateral episiotomy

Presentation Number: 068
OBSETETRIC ANAL SPHINCTER INJURIES (OASIS): 11-YEAR TREND ANALYSIS USING PATIENT EPISODE DATABASE FOR WALES (PEDW) DATA
S. ISMAIL[1], B. PUYK[2];
[1]Singleton Hosp., Swansea, United Kingdom, [2]NHS Wales Information Service, Cardiff, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To examine the trend of Obstetric Anal Sphincter Injuries (OASIS) using Patient Episode Database for Wales (PEDW) data.
Background:
Obstetric Anal Sphincter Injuries (OASIS) represent a serious delivery related morbidity, and can affect women in the short and long term, even with accurate diagnosis and adequate primary repair (1). A recent study using Hospital Episode Statistics online data in England over 4 years from 2002 till 2006 showed a steady, though non significant, rise in Obstetric Anal Sphincter Injuries (OASIS) (2). There was no significant change in the rate of operative delivery or episiotomy over the same time interval. This study however was limited to 4 years and 4 years behind, in line with data availability on Hospital Episode Statistics on line (www.hesonline.nhs.uk).
Method: A retrospective search of Patient Episode Database for Wales (PEDW) data, with the help of National Health Service (NHS) Wales Informatics Service. The rate of Obstetric Anal

Sphincter Injuries (OASIS) was calculated against the total number of vaginal deliveries. As the incidence of these injuries can be influenced by episiotomy and forceps delivery (3), the rate of episiotomy was calculated against the total number of vaginal deliveries and the rate of operative deliveries was calculated against total number of deliveries as well. The significance of rate differences across the study years was assessed using X^2 test and the significance of a trend in Obstetric Anal Sphincter Injuries (OASIS) was assessed using X^2 test for trend.

Result:

Data were available for 11 years from 1999 to 2009. The number and rate of episiotomy and Obstetric Anal Sphincter Injuries (OASIS) are shown in table 1 and illustrated in Fig. 1. The number and rate of various types of operative deliveries are shown in table 2 and illustrated in Fig. 2. A significant and steady over three fold increase in the incidence of Obstetric Anal Sphincter Injuries (OASIS) can be seen. The rate of episiotomy dropped initially then picked up again. The rate of forceps delivery increased whereas the rate of ventouse decreased. The rate of caesarean delivery showed a steady increase exceeding 40% at the end of the study period. This increase could be due to increased awareness and therefore better detection, but it can also be due other factors such as increased birth weight, use of epidural anaesthesia and prolonged second stage. It may also reflect changes in obstetric and midwifery practice in terms of perineal support as well as reduction of working hours, and thus training opportunities, which may reflect in the skill of performing episiotomy and instrumental delivery. This rise needs serious attention and evaluation in order to protect the pelvic floor of mothers and reduce the incidence of consequent morbidity, both short and long terms.

Conclusions:

The rate of Obstetric Anal Sphincter Injuries (OASIS) in Wales has increased three fold over 11 years from 1999 to 2009. This calls for serious attention to understand and address possible contributing factors, alongside other obstetric trends, to protect the anal sphincter as well as the pelvic floor of mothers.

References:

1. Short-term and long-term effects of obstetric anal sphincter injury and their management, Current Opinion in Obstetrics and Gynecology 2005; 17:605–610.

2. Obstetric Anal Sphincter Injuries (OASIS); 4-year trend analysis using hospital episode statistics data, International Urogynecology Journal 2010; 21:S374-5

3. Diagnosis and management of obstetric anal sphincter injury, Current Opinion in Obstetrics and Gynecology 2006; 18:141–146.

Year	Total number of vaginal deliveries	Number (%) of ventouse deliveries	Number (%) of forceps deliveries
1999	12,617	4,041 (32.03%)	228 (1.81%)
2000	11,749	3,676 (31.29%)	193 (1.64%)
2001	11,624	3,327 (28.62%)	192 (1.65%)
2002	11,460	3,016 (26.32%)	231 (2.02%)
2003	12,099	3,005 (24.84%)	312 (2.58%)
2004	12,216	3,107 (25.43%)	399 (3.27%)
2005	11,340	3,338 (29.44%)	425 (3.75%)
2006	10,889	3,485 (32.00%)	497 (4.56%)
2007	11,388	3,926 (34.47%)	601 (5.28%)
2008	11,336	4,318 (38.09%)	623 (5.50%)
2009	10699	4,300 (40.19%)	601 (5.62%)
X^2 (P value)		60611.65 (P<0.001)	7135.18 (P<0.001)
X^2 for trend (P value)			846.75 (P<0.001)

Table 1: The number and rate of episiotomy and Obstetric Anal Sphincter Injuries (OASIS).

Figure 1: Trend illustration of episiotomy and Obstetric Anal Sphincter Injuries (OASIS).

Year	Total number of deliveries	Number (%) of ventouse deliveries	Number (%) of forceps deliveries	Number (%) of caesarean deliveries
1999	19.201	2,112 (11.00%)	869 (4.53%)	6,584 (34.29%)
2000	18,526	2,180 (11.77%)	821 (4.43%)	6,777 (36.58%)
2001	18,521	1,949 (10.52%)	686 (3.70%)	6,897 (37.24%)
2002	18,301	1,866 (10.20%)	728 (3.98%)	6,841 (37.38%)
2003	19,149	1,928 (10.07%)	672 (3.51%)	7,070 (36.82%)
2004	19,410	2,018 (10.40%)	736 (3.79%)	7,194 (37.06%)
2005	18,839	2,131 (11.31%)	898 (4.77%)	7,499 (39.81%)
2006	19,169	2,084 (10.87%)	1,008 (5.26%)	8,280 (43.19%)
2007	19,507	1,942 (9.96%)	1,391 (7.13%)	8,119 (41.62%)
2008	19,734	1,932 (9.79%)	1,863 (9.44%)	8,398 (42.56%)
2009	19,109	1,762 (9.22%)	1,928 (10.09%)	8,410 (44.01%)
X^2 (P value)	108.60 (P<0.001)	6530.10 (P <0.001)	186582.74 (P < 0.001)	

Table 2: The number and rate of all types of operative delivery.

Figure 2: Trend illustration of various types of operative delivery.

Presentation Number: 069

DIFFERENT PATTERNS OF PELVIC FLOOR DYSFUNCTION IN FORCEPS AND VACUUM DELIVERIES

M. ALCALAY, S. BRECHER, A. KALTER, E. SCHIFF, V. EISENBERG;

Dept. of Obstetrics and Gynecology, Chaim Sheba Med. Ctr., Ramat Gan, Israel.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

To compare the imp\act of a first instrumental delivery on pelvic floor symptoms and transperineal ultrasound findings.

Background:

The first vaginal delivery is one of the major etiological factors for pelvic floor dysfunction. In primiparous women, both vacuum and forceps deliveries significantly increase postpartum new symptoms of anorectal dysfunction, and vacuum deliveriy also increases new symptoms of urinary incontinence (1). Levator avulsion is prevalent after instrumental and normal vaginal deliveries, both on MRI and ultrasound studies, but is not documented after elective cesarean section (2,3). However, the

effect of this injury on pelvic floor dysfunction is not fully understood.

Methods:

In this longitudinal cross sectional study we recruited primiparous women who were delivered by vacuum or forceps more than one year prior to recruitment, and compared them to primiparous women who delivered by elective cesarean section for breech presentation.

All women completed the following questionnaires: PFDI-20, PFIQ, Cleveland Clinic Incontinence Score (CCIS) and a sexual function questionnaire. Transperineal pelvic floor ultrasound was performed with an abdominal RAB 4–8 MHz probe (GE Kretz Voluson 730 expert system) supine and after voiding. Volume datasets were reviewed offline (GE Kretz 4DView 5.0) for anal sphincter characteristics, hiatal dimensions and levator trauma, blinded against clinical data. Findings were compared between groups and correlated with symptoms. Statistical analysis was performed with SPSS (p-value<0.05 for significance).

Results:

6087 women had their first delivery between 2008 and 2009 at our institution, of which: 93 forceps (F), 772 vacuum (V), and 362 elective cesarean deliveries (CS). Women undergoing a repeat delivery and those after combined vacuum-forceps delivery were excluded. In total, 27 women in the forceps group, 17 women in the vacuum group and 13 women in the CS group agreed to participate and completed the study protocol. The patients had a similar time interval from delivery (19 months), age, BMI, fetal weight and neonatal head circumference. One woman in each of the vacuum and forceps groups was diagnosed with a 3rd degree tear at the time of delivery.

Bladder symptoms were more prevalent in the V group, with a significantly higher incidence of urge incontinence (56.2%, 29.6%, 15.4% in V, F and CS groups respectively, $p<0.05$), and non significant differences in stress incontinence symptoms (47.1%, 34.6%, 16.7% respectively). Anorectal symptoms were more frequent in the F group, with a significantly higher incidence of flatus incontinence (58%), compared to the V group (29.4%, $p=0.05$) and the CS group (0%, $p<0.01$). The total incontinence score (CCIS) was significantly higher in the F group (5.4), than in the V group (2.2) or CS group (0%, $p<0.05$). Dyspareunia was more prevalent in the V group but did not reach significance, and quality of life parameters did not differ between the groups.

On ultrasound, anal sphincter defects were found in 4 and 3 patients in the F and V groups, respectively, and in none in the CS group. There were, therefore, three occult tears in the V group and one in the V group (NS).

Levator hiatal dimensions and avulsion defects are described in Table 1. All hiatal dimensions were significantly larger in the F group compared to the CS group ($p<0.03$), while hiatal area at rest was also larger in Group V ($p<0.003$). Bilateral avulsion defect was significantly more common after F deliveries, while there were no avulsion defects in women undergoing elective cesarean section. There was a statistically significant correlation between bilateral avulsion defects and flatus incontinence ($p=0.037$), but none with urinary stress or urge incontinence.

Table 1: Levator hiatal dimensions and avulsion defects on transperineal ultrasound

	Forceps (n=27)	Vacuum (n=17)	CS (n=13)	P values F vs. CS	P values V vs. CS	P values V vs. F
Ballooning (%)	17 (63)	4 (23.5)	4 (30.8)	0.058	NS	0.01
Avulsion (%)	24/27 (88.9)	7/17 (41.2)	0	<0.001	0.011	<0.001
Bilateral avulsion (%)	17/27 (66.7)	3/17 (13.6)	0	<0.001	NS	<0.001

Conclusions:

Different patterns of sustained pelvic floor symptoms and levator trauma were found among primiparous patients who were delivered by vacuum or by forceps. However, these symptoms did not significantly affect their quality of life. The significantly higher prevalence of bilateral avulsion defects in the forceps group can partly explain their symptoms, and may increase the future risk of pelvic floor dysfunction in these women. Further follow-up and larger studies are needed to clarify these findings.

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Presentation Number: 070

NEONATAL BODY TRUNK MEASUREMENTS ARE A USEFUL PREDICTOR OF BIRTH INJURIES

N. HARITA[1], M. KARIYA[2], T. HAYASHI[1], K. K. SATO[1], K. NAKAMURA[2], G. ENDO[1], K. NARIMOTO[2];
[1]Osaka City Univ., Osaka, Japan, [2]Ishida Hosp., Hirakata, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

We investigated which anthropometric measurements of neonates and mothers are the most useful to evaluate the relation of disproportion between neonatal size and maternal soft birth canal

and surrounding tissue (feto-maternal perineum disproportion) to the risk of severe birth injuries.

Background:

Severe birth injuries, that is, third- and fourth-degree perineal lacerations, have been associated with anal incontinence [1] and dyspareunia [2], which decreases quality of life for the rest of affected women's life. Previous studies have reported that Asian ethnicity was one of risk factors for severe lacerations during vaginal delivery [3]. We hypothesized that feto-maternal perineum disproportion due to their substantially smaller build would contribute to a higher rate of severe lacerations among Asian women and conducted this analysis to investigate our hypothesis.

Methods:

The study participants were 481 Japanese primiparous women who delivered a singleton baby by vaginal delivery. These subjects were selected from all the participants enrolled between November 2006 and April 2008 in our observational cohort study. At entry, information on maternal age, height, pre-pregnant body weight, and parity was collected. Neonatal measurements were taken soon after delivery. Diagnosis of perineal lacerations was made by the obstetrician who attended the delivery. Body mass index and ponderal index (PI) as one-tenth of the weight in kilograms divided by the cubic height in meters were calculated to assess body builds of the participants and their offspring, respectively. We analyzed the correlation of various indices that could reflect feto-maternal perineum disproportion; neonatal height/maternal height ratio, neonatal height/maternal height ratio, head circumference/maternal height ratio, chest circumference/maternal height ratio and PI/maternal height ratio to the risk of severe birth injuries, using multiple logistic regression models.

Results:

Of 481 participants, 19 had severe birth injuries (18 with third-degree and 1 with fourth-degree perineal lacerations). On crude models, there are no maternal factors which were significantly associated with severe birth injuries. PI was the only neonatal factor associated with severe birth injuries (OR 1.60 for 1 SD increase of PI, P=0.044). (Figure) Among possible surrogates of feto-maternal perineum disproportion, greater chest circumference/maternal height ratio was the most strongly associated with the severe birth injuries (OR 1.75 for 1SD increase in the ratio, P= 0.014). (Figure) On multivariate models, after adjustment for maternal age, gestational age, and maternal height (maternal height was used only for PI), the effects of PI and chest circumference/maternal height ratio on severe birth injuries were maintained with a significant OR of 1.68 and 1.92, respectively. We also adjusted for vacuum extraction procedures, but the associations were still significant.

Conclusions:

Of neonatal and maternal anthropometric factors, neonatal PI was significantly associated with severe birth injuries. Chest circumference/maternal height ratio was the most robust factor among various neonatal measurements to maternal height ratios. These findings suggested that neonatal body build and disproportion between the neonatal body trunk and maternal height are significantly associated with severe birth injuries. Although our study utilized neonatal measurements obtained after delivery, ultrasound findings of fetal size during antenatal care may be useful for prediction of severe birth injuries. In that case, the measurements of body trunk could be a more useful predictive index than fetal cephalic measurements. Further study is needed to confirm this hypothesis.

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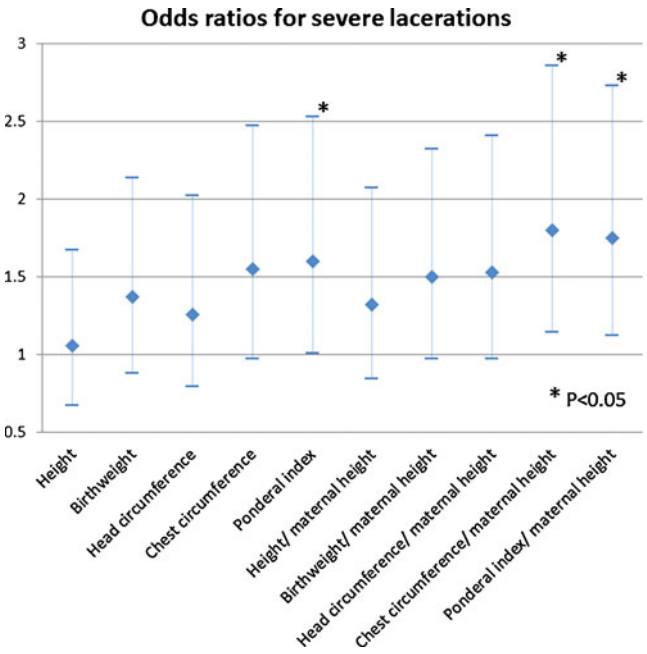

Presentation Number: 071

IMPACT OF OBSTETRIC ANAL SPHINCTER INJURY (OASI): ARE 4TH DEGREE TEARS REALLY WORSE THAN 3RD DEGREE TEARS?

S. JHA, P. AMARAD, S. TRACEY, L. HUNT, S. RADLEY;
Jessop Wing, Royal Hallamshire Hosp., Sheffield, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objectives:

The aim of this study was to evaluate and compare the outcomes of 3rd and 4th degree Obstetric Anal Sphincter Injury (OASI) and their impact on overall bowel, urinary, vaginal and sexual function.

Background:

OASI complicates 1–4% of vaginal deliveries. It is believed that 4th degree tears have a greater impact on outcomes than 3rd degree tears. In addition, though there are many published reports of impact of OASI in terms of bowel symptoms, there is limited data on the impact on urinary, vaginal or sexual function and there are no reports comparing outcomes of these aspects of pelvic floor function in women with 3rd and 4th degree tears.

Methods:
This was a retrospective review of a database used in routine clinical practice for patient symptom assessment. Fishers Exact test was used to compare the outcomes of 3rd and 4th degree tears on painful evacuation, faecal urgency, faecal incontinence (liquid and solid stool) and flatus incontinence. In addition, overall bowel, vaginal, urinary and sexual symptoms were evaluated on a scale of 0–100 in women with 3rd and 4th degree tears and were compared using Mann–Whitney u Test.

Results:
800 women suffered OASI in this tertiary centre between 2003 and 2009. Data were available for pelvic floor symptoms for 330 women who completed a validated pelvic floor questionnaire (ePAQ) as a part of their evaluation in the Perineal Trauma clinic, 3–7 months after sustaining OASI. Of these 301 had a 3rd degree tear (A, B or C) and 29 had a 4th degree tear.

9.3% patients reported incontinence of liquid stool and 6.6% of solid stool. 28.2% women reported flatus incontinence. 33% women reported faecal urgency and 37.7% painful evacuation. There was no difference in any of these symptoms when comparing 3rd and 4th degree tears (Table 1).

Table 2, 3,4 and 5 show the impact of OASI on bowel, urinary, vaginal and sexual problems. No difference was demonstrated when comparing 3rd and 4th degree tears on any aspect of pelvic floor function.

Conclusion:
Women who have 3rd degree tears have a similar outcome to women suffering 4th degree tears. Women who suffer OASI are at a significant risk of associated urinary, vaginal and sexual problems in addition to bowel problems however this was not influenced by the grade of OASI.

Perineal trauma clinics provide a good opportunity to address these problems and therefore should have a holistic approach in evaluating and managing women with OASI. They should evolve strategies to help women with urinary, vaginal and sexual problems in addition to managing bowel problems.

Table 1. Outcomes of repair; n= 330

	3rddegree tears	4th degree tears	P values
Painful evacuation	113/301	13/29	0.281
Urgency	101/301	9/29	0.480
Inco Flatus	85/301	9/29	0.449
Inco solid stools	18/301	4/29	0.115
Inco liquid stools	29/301	2/29	0.472

Table 2. Bowel Function n= 330 (Score 0–100; 0 = asymptomatic 100 = severe symptoms)

	0	>0 and <50	51–75	76–100	P value comparing 3rd and 4th degree tears
IBS	123 (36.7%)	203(50.5%)	5 (1.5%)	0	0.374
Constipation	128 (38.3%)	185(55.5%)	14 (4.2%)	4 (1.2%)	0.787
Evacuation	155(46.3%)	170(51.0%)	4 (1.2%)	1 (0.3%)	0.642
Continence	206 (61.5%)	122 (36.5%)	12 (3.6%)	2(0.6%)	0.797
QoL	225(67.3%)	92 (27.5%)	11 (3.7%)	2 (0.68%)	0.394

Table 3: Urinary Symptoms n= 330 (Score 0–100; 0 = asymptomatic 100 = severe symptoms)

	0	>0 and <50	51–75	76–100	P value comparing 3rd and 4th degree tears
Pain	282 (83.9%)	49 (14.6%)	2 (0.6%)	0	0.742
Voiding	306 (91.3%)	27 (8.0%)	0	0	0.263
OAB	184 (54.9%)	147 (44.0%)	3 (0.9%)	0	0.885
SUI	201 (60%)	126 (37.7%)	5 (1.5%)	1 (0.3%)	0.675
QoL	254 (75.8%)	71 (22.1%)	6 (1.8%)	4 (1.2%)	0.542

Table 4: Vaginal Symptoms n= 330 (Score 0–100; 0 = asymptomatic 100 = severe symptoms)

	0	>0 and <50	51–75	76–100	P value comparing 3rd and 4th degree tears
Pain	169 (50.4%)	154 (46.1%)	4 (1.2%)	0	0.876
Capacity	242 (72.2%)	74 (22.1%)	4 (1.2%)	4 (1.2%)	0.392
Prolapse	270 (80.6%)	53 (15.8%)	3 (0.9%)	1 (0.3%)	0.539
QoL	221 (66%)	98 (29.3%)	3 (0.9%)	7 (2.1%)	0.846

Table 5: Sexual function n= 330 (Score 0–100; 0 = asymptomatic 100 = severe symptoms)

	0	>0 and <50	51–75	76–100	P value comparing 3rd and 4th degree tears
Urinary	242 (72.5%)	67 (20%)	7(2.1%)	1 (0.3%)	0.954
Bowel	262 (78.4%)	43 (12.8%)	7 (2.1%)	0	0.999
Vaginal	162 (48.4%)	109 (32.6%)	36 (10.7%)	8 (2.4%)	0.630
Dyspareun	180 (53.7%)	68 (20.3%)	8 (2.4%)	4 (1.2%)	0.802
Sex life	93 (27.8%)	182 (54.4%)	26 (7.8%)	12 (3.6%)	0.701

Presentation Number: 072

PREVALENCE OF URINARY INCONTINENCE IN A MULTIETHNIC POPULATION OF PREGNANT WOMEN

K. BØ[1], L. SLETNER[2], K. MØRKRID[2], A. K. JENUM[2];
[1]Norwegian Sch. of Sport Sci., Oslo, Norway, [2]Oslo Univ. Hosp., Aker, Oslo, Norway.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To investigate the prevalence of urinary incontinence (UI) in a multiethnic population of pregnant women using The International Consultation on Incontinence Questionnaire- urinary incontinence-short form (ICIQ-UI SF), analyse associations of known risk factors and compare the different ethnic groups.

Background:
Newer studies have found a lower prevalence of stress urinary incontinence (SUI) in African, Afro-American and Asian women compared to Caucasian groups (1). There are few studies comparing UI prevalence between different ethnic minority groups living in the same residential area. Pregnancy and childbirth are known risk factors for development of female UI (1). However, in a recent systematic review no studies compared prevalence of UI in a multiethnic pregnant population (1).

Methods:
This study presents cross sectional data from a population- based study of multiethnic pregnant women (2). All pregnant women in three administrative city districts attending the Child Health Clinics for antenatal care were asked to participate in the study. General practitioners were asked to remit pregnant women to the clinics early in pregnancy. Inclusion criteria were; living in one of the districts, give birth at one of two study hospitals, be in gestational week≤20, not suffering for diseases necessitating intensive hospital follow-up, able to communicate in Norwegian, Arabic, English, Sorani, Somali, Tamile, Turkish, Urdu or Vietnamese and being able to give informed consent. Of the 1114 invited women, 823 women participated in the study (74% response rate), and 772 of them reattended at visit 2 (gestational week 28 ±2). Trained midwifes interviewed the women, and questions on prevalence and degree of UI were posed at visit 2 with ICIQ UI SF (3). Background variables are presented as frequencies, percentages or means with standard deviations (SD). X^2 test, ANOVA and Independent *t*-test were used to compare categorical and continuous background variables between those with and without UI. Associations were estimated by logistic regression analysis, and the covariates included in the analysis were: age, parity, pre-pegnancy BMI, educational level, ethnicity, urinary tract infection and participation in regular exercise. The results are presented as crude (cOR) or adjusted odds ratios (aOR). A *p*-value of <0.05 was considered statistically significant.

Results:
The study population consisted of 368 women from America/Europe, 192 from South Asia, 40 from East Asia, 117 from Middle East/Sentral Asia/North Africa and 54 from South Sahara Africa. Mean age of the total study population was 29.4 years (SD 4.9). The proportion of nulliparous and multiparous women was 45.8% and 54.2%, respectively. Mean pre-pregnancy BMI was 24.6 (SD 4.8) and 44.2% had college/university education. Twenty- three% reported to be regular exercisers and 11.1% reported urinary tract infections. There was a statistically significant difference in UI between ethnic groups varying from 25.5 (South Sahara Africa) to 46.1 America/Europe (p=.04). Between 66% and 87.5% of incontinent women reported SUI. There was a statistically significant difference in reported frequency of incontinence, incontinence bother and ICIQ UI SF between groups (p=.04, p<.001 and p<.001, respectively). Groups from East Asia and South Sahara Africa were more bothered. When comparing women with and without UI, there was a statistically significant difference in age, parity and ethnicity. Both univariate and multivariate analyses confirmed these results with aOR of 1.05 (95% CI: 1.01–1.09) for age, 2.33 (95% CI: 1.66–3.27) for parity and 0.39 (95% CI: 0.19–0.83) for origin from South Sahara Africa.

Conclusions:
As far as we have ascertained this is one of the first epidemiological studies on UI in a multiethnic pregnant population living in the same residential area, using the ICIQ UI SF. Established risk factors such as age and parity were associated with UI in this group of multiethnic pregnant women. Ethnic origin from South of Sahara Africa was associated with continence during pregnancy. One limitation of the study is a small sample size in two of the ethnic groups.

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Presentation Number: 073

PREDICTORS OF CARE SEEKING IN WOMEN WITH URINARY INCONTINENCE

V. A. MINASSIAN, M. J. LICHTENFELD, H. SUN, W. F. STEWART;
Geisinger, Danville, PA.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The goal of our study is to determine factors associated with care-seeking and care-delivery in a cohort of women age 40 and over with urinary incontinence **(UI).**

Background:
Urinary incontinence is a highly prevalent condition, affecting women of all ages and with a significant impact on quality of life. Although the high prevalence and burden of UI on health status and quality of life should motivate care seeking, paradoxically only a small proportion of the population appears to seek help.

Methods:
The General Longitudinal Overactive Bladder Evaluation—UI **(GLOBE-UI)** is a population-based study on the natural history of UI and its sub-types in women ≥40 years of age. Study participants were randomly selected and asked to fill the bladder health survey **(BHS),** a validated UI questionnaire. The BHS included 2 lifetime UI questions. Those responding negatively to both questions or had insignificant symptoms were non-cases. Conversely, women who answered "yes" to the 2 UI questions, or with significant UI symptoms were cases. The BHS also included the Sandvick severity index, IIQ-7, UDI-6, 2 stress UI, 2 urgency UI, and 5 adaptive behavior questions. Composite scores were derived for questions within the same group. Our cohort comprised of women who qualified as cases based on the responses to the BHS. We then divided these women into two groups (cases and controls) based on their clinical UI diagnosis. This was based on electronic health records **(EHR)** UI ICD9 diagnoses, history of bladder control medications, CPT codes for UI surgery, or a clinic visit to physical therapy, urogynecology and female urology. Other health parameters extracted from the EHR were smoking and alcohol history, and other co-morbid conditions included in the Charlson index. Univariate correlations were examined between the 2 groups including demographic and UI parameters (UI subtype score, severity of UI symptoms, bother, behavior and impact on quality of life, and duration of symptoms), total number of outpatient visits and inpatient hospitalizations during the study time period. Variables found to have a significant relationship with UI ICD9 case status were incorporated into further multivariate analysis. In the multivariate analysis, a stepwise selection procedure was used to identify risk factors for UI care seeking and receipt. Categorical and continuous versions of variables were examined when applicable. All statistical tests were 2-sided with a P value of less than 0.05 considered as a cut-off for statistical significance.

Results:
There were a total of 1,326/3,221 (41%) respondents who were classified as having UI based on the BHS. Of those, only 367 (28%) women had a UI ICD9 diagnosis in their EHR. Cases were older than controls (mean age: 64 vs 59 years), had a higher BMI (mean BMI: 41 vs 38 kg/m2), had a higher parity ≥1 (94% vs 89%), were less likely to be married (59% vs 68%), had lower education level (high school or less: 54% vs 43%), had a higher prevalence of hysterectomy (40% vs 29%), and were less likely to drink alcohol (32% vs 43%). Before adjustment, cases (vs. controls) had higher scores in their UI subtype, UDI-6, IIQ-7, UI behavior, Sandvick severity scale and with a longer duration of UI symptoms. Furthermore, cases also had a higher co-morbidity Charlson index score, and a higher number of doctor visits (all p-values<0.05). After adjustment, predictors that remained significant for case status were parity, higher scores on urgency UI, UDI, UI behavior, and a higher number of doctor visits (see table).

Discussion:
Although UI is a highly prevalent condition, less than 30% of our cohort sought or received care for their UI. Factors associated with care-seeking or care-delivery were parity, urgency UI subtype, higher UI bother and impact on behavior, and women with a higher number of doctor visits. There are many reasons why patients do not seek care for UI, including lack of health care availability, poor finances, embarrassment from UI symptoms, and others. This study sheds light on potential important predictors, previously not well established, associated with UI help seeking in a setting where health care is already available.

Table: Logistic Regression Model for Factors Associated with UI Help Seeking

	Odds Point Estimate	95% Wald Confidence	Limits	P-value
Urgency UI	1.112	1.02	1.21	0.02
UI Severity	1.287	0.97	1.71	0.08
UI behavior	1.140	1.03	1.3	0.001
UDI	1.078	1.00	1.16	0.04
Parity	1.870	1.00	3.51	0.05
Doctor visits	1.024	1.02	1.03	<0.001

Presentation Number: 074

PREVALENCE OF PELVIC FLOOR DYSFUNCTION IN PRIMIPAROUS WOMEN AT 1 YEAR AFTER DELIVERY

C. DURNEA, V. CARLSON, A. KHASHAN, L. C. KENNY, B. A. O'REILLY;
Cork Univ. Maternity Hosp., Cork, Ireland.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To identify the risk factors for pelvic floor dysfunction and delineate the group of the patients who might be at higher risk of having these complications.

Background:
Pregnancy and childbirth are acknowledged as major aetiological factors in subsequent Pelvic Floor Dysfunction (PFD). It is still unclear however, whether it is parturition or the delivery or both directly responsible.
This study aims to look at various factors involved in pregnancy amongst a group of primagravid women to identify potential cause and effect.
Methods:
We are carrying out a prospective, longitudinal, observational cohort study as part of the SCOPE (Screening for Pregnancy Endpoints) Ireland study (www.scopestudy.net), an international, multicenter pregnancy biobank initiative with the aim of developing predictive tests for adverse pregnancy outcome.
Low risk, primiparous women are recruited at15 weeks' gestation and complete a standardised, validated questionnaire (Australian Pelvic Floor Questionnaire regarding bladder, bowel, prolapse and sexual function with a particular focus on pre-pregnancy symptoms. Detailed pregnancy outcomes, including mode of delivery, duration of labour, fetal biometry, are collected shortly after delivery. Women then complete the same questionnaire approximately12–18 months after delivery.
All patients are delivered in a single tertiary maternity hospital following the same labour ward protocols.
Data was analyzed using SPSS statistical package.
Results:
224 women met the inclusion criteria. 99% of participants are Caucasian.
We have detected a high background prepregnacy incidence of urinary, bowel and sexual dysfunctions (urgency-39.9%, urge incontinence-17.0%, stress incontinence-35%, bowel urgency-43.9%, bowel frequency-15.8%,dyspareunia −30.4%,).
The prenatal asymptomatic women had a high postnatal incidence of urinary urgency [OR-8.6], stress incontinence [OR-12.0], defecation frequency [OR-9.2], vaginal laxity [OR-5.1] and vaginal pressure [OR-4.3].
Amongst postnatal women with severe PFD, the length of the second stage of labour was prolonged as compared to asymptomatic group (Mean-82 min vs. 54 min). Similarly women with higher scores of PFD had a higher rate of instrumental delivery (50% vs. 23%), and asymptomatic women had higher spontaneous delivery rate (49% vs. 31%). Furthermore, asymptomatic women were found to have higher Caesarean section rate (27% vs. 19%).

Questionnaire Symptoms	Pre-Pregnancy Incidence	Post-pregnancy incidence at 12–18 months postnatal		OR	CI $P<0.005$
		Asymptomatic pre-pregnancy	All Post/Natal Symptomatic cases		
Urinary Urgency	89(39.9%)	37(27.6%)	107(47.8%)	8.6	4.6–16.0
Urge Incontinence	38(17.0%)	43(23%)	67(30%)	5.9	2.8–12.3
Stress Incontinence	44(19.7%)	63(35%)	102(45.5%)	12.0	4.8–29.8
Faecal Urgency	97(43.9%)	41(33%)	111(49.6%)	4.7	2.7–8.3
Defaecation Frequency	35(15.8%)	15(8%)	31(13.8%)	9.2	4.0–21.4
Vag. Pressure/heaviness	5(2.3%)	18(9.7%)	22(10%)	4.3	1.17–15.7
Poor vaginal sensation during intercourse	24(11.1%)	35(18%)	41(19%)	3.5	1.5–7.8
Vaginal Laxity	7(3.2%)	38(18%)	41(18.7%)	5.1	1.75–15.0
Dyspareunia	66(30.4%)	46(30%)	81(37%)	3.7	2.0–6.6

Correlation between Pelvic Floor Dysfunction (PFD) score and risk factors

PFD score	Age	BMI	G.A. at delivery (w)		1st stage Hours	2nd stage Min.	Birthweight	Head circumference
0–1	30.8	25.0	39	+2	5.7	54.0	3394.7	34.8
0–10	30.7	25.3	39	+3	5.2	68.8	3452.7	34.3
10–24	31	24.2	39	+3	5.4	82.8	3424.2	35.1

Conclusion:
This study demonstrated a high rate of pre-pregnancy pelvic floor dysfunction which has not been described previously.
There is a statistically significant increase in urinary, bowel and sexual dysfunction as a result of first pregnancy and labour.
We have confirmed prolonged second stage and instrumental delivery as significant risk factors for PFD at12–18 months following a first delivery as compared with a normal vaginal delivery. Maternal age and BMI and fetal birthweight, head circumference and gestation at delivery do not significantly increase the risk of severe pelvic floor dysfunction. Delivery by Caesarean section is associated with a non-significant protective role for subsequent severe pelvic floor dysfunction.

Presentation Number: 075

PREDICTORS OF AND CARE-SEEKING FOR ACCIDENTAL BOWEL LEAKAGE: A COMMON YET UNDER-DIAGNOSED CONDITION

H. W. BROWN[1], S. WEXNER[2], M. SEGALL[3], E. LUKACZ[1]; [1]UCSD, San Diego, CA, [2]Cleveland Clinic Fndn., Weston, FL, [3]Los Gatos, Los Gatos, CA.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objectives:
Among community-dwelling US women, to: (1) Define the prevalence of fecal incontinence (FI) and identify associated factors and (2) Compare care-seeking behaviors for FI and urinary incontinence (UI)

Background:
Estimates of FI in community-dwelling US women range from 7% to 24% (1–3). Associated factors include obesity, diabetes, stroke, irritable bowel syndrome (IBS), diarrhea, urinary incontinence, and rectocele; data are conflicting about race, parity and age (1–3). Like UI, FI is common and negatively impacts quality of life, but women are reluctant to discuss these sensitive issues with a doctor.

Methods:
An internet-based survey of women ≥45 years was conducted. Participants were asked about accidental leakage of urine, liquid and solid stool using questions derived from validated questionnaires. Information was collected on demographics, medical history, coping and care-seeking. FI was defined as any loss of solid or liquid stool in the past 12 months; UI was defined as any episode of urinary leakage or incontinence in the past 12 months. Women with FI were asked how they would prefer this leakage be described. Chi square testing, univariate and multivariate logistic regression models were used to identify factors associated with FI. All factors associated with FI with a p-value<0.10 on univariate analyses were included in the multivariate model. Chi square testing was used to compare care-seeking for FI and UI.

Results:
Of 6,873 women surveyed, 5,817 (85%) responded; 80% were White, 9% African-American, 6% Hispanic, and 5% other, with median age 55–59 (range 45 to >85); 88% had health insurance. The prevalence of FI and UI in the past 12 months were 19% (n=1,096; 95% CI 17.8–19.9%) and 46% (n=2,664, 95% CI 44.5–47.1%); 13% (n=772, CI 12.4–14.1%) had both FI and UI.

Among 1,096 respondents with FI, only 31% (339) had heard the term "fecal incontinence" and 40% (442) had heard "bowel incontinence." When asked which term they would prefer, 71% (667) preferred "accidental bowel leakage;" 23% (211) preferred "bowel incontinence" and 6% (60) preferred "fecal incontinence."

Table 1 presents the prevalence of ABL stratified by potential associated factors and results of the multivariate logistic regression model. IBS, UI, inflammatory bowel disease, prior stroke, age 55–64, diabetes mellitus or pre-diabetes, and prior vaginal delivery were significantly associated with an increased risk of ABL, while being married, African-American race, Native American race, and annual income >$40 K were protective (Table 1).

Table 1: Predictors of Accidental Bowel Leakage

Characteristic	% with ABL (n)	X^2 (p-value)	Multivariate OR (95% CI)	p-value
Age group				
45–54	15.6 (314)	<0.001	1.00 (referent)	0.002
55–64	21.7 (402)		**1.371 (1.140, 1.650)**	**0.001**
65–74	19.0 (330)		1.021 (0.832, 1.253)	0.844
75+	23.1 (50)		1.146 (0.762, 1.723)	0.513
Race				
White	20.1 (929)	<0.001	1.00 (referent)	0.026
Black/African-American	12.2 (67)		**0.676 (0.505, 0.906)**	**0.009**
Asian	13.3 (22)		0.834 (0.497, 1.399)	0.491
Hispanic	16.7 (56)		0.776 (0.557, 1.083)	0.136
Native American	15.0 (9)		**0.435 (0.201, 0.941)**	**0.034**
Other	17.6 (13)		0.945 (0.472, 1.892)	0.874
Income				
<$40,000 per year	23.0 (561)	<0.001		
$40,000 + per year	16.5 (471)		**0.841 (0.716, 0.986)**	**0.033**
Education				
Less than high school	21.8(47)	0.020		
Completed high school	18.9 (413)			
Some college	20.5 (362)			
College graduate +	16.6 (274)			
Not employed	20.8 (638)	<0.001	0.857 (0.732, 1.004)	0.056
Employed	16.6 (458)			
Single/divorced/widowed	22.4 (505)	<0.001		

Married	16.6 (591)		**0.649 (0.551, 0.764)**	**<0.001**
Health insurance	18.6 (954)	0.270		
No health insurance	20.4 (142)			
Has a PCP	19.2 (1001)	0.025		
No PCP	15.5 (95)			
Has IBS	42.6 (437)	<0.001	**3.761 (3.191, 4.432)**	**<0.001**
No IBS	13.8 (659)			
Has IBD	47.8 (54)	<0.001	**2.680 (1.717, 4.184)**	**<0.001**
No IBD	18.3 (1042)			
Has had a stroke	31.9 (65)	<0.001	**1.562 (1.095, 2.227)**	**0.014**
No prior stroke	18.4 (1031)			
No DM	17.0 (763)	<0.001	**1.298 (1.098, 1.534)**	**0.002**
DM or pre-DM	25.2 (333)			
Continent of urine	10.3 (324)			
Had UI in past year	29.0 (772)	<0.001	**3.032 (2.594, 3.543)**	**<0.001**
No prior delivery	15.7 (134)	<0.001	1.00 (referent)	0.001
Prior C-section only	12.1 (71)		0.784 (0.556, 1.107)	0.167
Prior vaginal delivery	20.4 (891)		**1.278 (1.020, 1.602)**	**0.033**

Abbreviations: OR - Odds ratio; CI - Confidence interval; PCP - Primary care provider; IBS - Irritable Bowel Syndrome; IBD - Inflammatory Bowel Disease; DM - Diabetes mellitus; UI - Urinary incontinence

Only 8% (76) of women with ABL had been diagnosed by a doctor, as compared with 25% (644) of women with UI ($p<0.001$). Care-seeking data were available for 86% (938) of women with ABL and 97% (2,588) of women with UI. Of women with ABL, 28% (271) were not at all comfortable or somewhat uncomfortable discussing this condition with their doctor, as compared to only 15% of women with UI ($p<0.001$). Similarly, 29% (268) of women with ABL, vs. 47% (1,212) of women with UI, had ever discussed their condition with a doctor ($p<0.001$). More than half of women with ABL or UI who discussed their condition did so with their family physician (Fig. 1).

Conclusions:

FI is common, and the overwhelming majority of women with it would prefer to use the term "accidental bowel leakage" (ABL) to describe it. In this large sample IBS and UI were strongly associated with ABL. African-American race was protective. Prior vaginal delivery was associated with ABL. The association of age and ABL remains unclear. Women with UI are more likely than women with ABL to discuss their condition with a doctor.

References:

1. Dis Colon Rectum 2006;49(6):841–51. 2. Am J Gastroenterol 2005;100(4):905–9. 3. Gastroenterology 2010;139(5):1559–66.

Presentation Number: 76

THE EFFECT OF PROLAPSE REPAIR ON SEXUAL FUNCTION

A. DUA[1], S. JHA[1], S. C. RADLEY[1], G. L. JONES[2], A. G. FARKAS[1];

[1]Sheffield Teaching Hosp. NHS Fndn. Trust, Sheffield, United Kingdom, [2]Sheffield Univ., Sheffield, United Kingdom.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

To determine the effect of different forms of surgery for pelvic organ prolapse on female sexual function.

Background:

Pelvic organ prolapse occurs in 40% of parous women and is associated with significant sexual symptoms [1]. The effect of different forms of prolapse surgery on sexual function is poorly understood. The majority of studies to date have included small numbers of patients and employed non-validated outcome measures [2].

Methods:

Data were collected prospectively for women undergoing prolapse repair between 2008 and 2010 and were stratified into four groups: 'Posterior repair', 'Anterior repair', 'Anterior repair with Vaginal Hysterectomy' and 'Combined Anterior and Posterior repair'. The electronic pelvic floor assessment questionnaire (ePAQ) was used to assess symptoms. The sexual dimension of ePAQ automatically computes domain scores for sexual problems related to urinary, bowel and vaginal symptoms and scores for dyspareunia and general sex life on a scale of 0–100 (0 = best possible, 100 = worst possible health status). Only women who gave consent for use of their data were included in the analysis. ePAQ was completed both pre and 3–6 month post-operatively. Results were analysed using SPSS. Preoperative scores for each domain were compared with postoperative scores for each form of surgery (Student t test). Individual symptoms in these dimensions were compared using Wilcoxon signed rank test.

Results:

A total of 123 women who completed the ePAQ sexual dimension both pre and postoperatively were included. Sexual symptoms secondary to prolapse (avoidance of sex, partner avoidance, anxiety and overall interference due to prolapse) and dyspareunia (dryness, lack of sensation, discomfort, tightness and obstruction) were significantly improved 3–6 months following anterior repair (with or without hysterectomy). These sexual symptoms also

improved following posterior repair or when posterior repair was combined with anterior repair, but this improvement was not statistically significant (Table 1). In women undergoing posterior repair, sub-group analysis found a non-significant trend towards greater improvement in sexual function, particularly dyspareunia, in women who *did not* undergo concomitant perineorrhaphy, though these women were generally younger and only 11 women were analysed in the perineorrhaphy group.

Conclusion:
Anterior repair is associated with substantial and significant improvement in sexual function. Although women undergoing posterior repair reported improved sexual function, these changes were less substantial and did not reach significance.

References:
1. J Urol. 2005; 173(5): 1669–72
2. Eur J Obstet Gynecol Reprod Biol. 2006; 129(2):104–10

Table 1: Change in sexual function domain scores following prolapse repair

	Anterior repair (n=28)			Anterior Repair + Vaginal hysterectomy (n=36)			Posterior repair (n=43)			Posterior repair + Anterior repair (n=16)		
Domain	**Mean Pre op score**	**Mean post op score**	**T test**	**Mean Pre op score**	**Mean post op score**	**T test**	**Mean Pre op score**	**Mean post op score**	**T test**	**Mean Pre op score**	**Mean post op score**	**T test**
Sex (vaginal)	48.3	15.8	<0.001	36.4	8.0	<0.001	38.6	30.7	0.27	41.2	21.2	0.09
Dyspareunia	36.4	12.9	<0.001	21.5	6.5	<0.001	30.9	21.8	0.10	29.3	22	0.45

Presentation Number: 77

PELVIC FLOOR SYMPTOMS AND SEXUAL FUNCTION IN OBESE WOMEN SEEKING BARIATRIC SURGERY: A PRE AND POST-OPERATIVE ASSESSMENT

M. A. BARKER, A. FELLNER, G. KERLACKIAN, S. KLEEMAN, R. PAULS;
Good Samaritan Hosp., Cincinnati, OH.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To assess the effect of weight loss on pelvic floor symptoms, sexual function, and body image during sexual activity in obese women after bariatric surgery.

Background:
Two thirds of morbidly obese women preparing for bariatric surgery suffer from urinary incontinence and many have impaired sexual function across all domains when presenting for bariatric surgery.[1, 2]

Methods:
A prospective observational study of women undergoing bariatric surgery. Women were questioned pre- and post-operatively using the Pelvic Floor Dysfunction Index 20 (PFDI-20), Female Sexual Function Index (FSFI), and Body Exposure during Sexual Activities Questionnaire (BESAQ). Their scores along with age, race, weight loss, parity, co-morbidities, and type of surgery were obtained from participants before undergoing bariatric surgery and 6 months post-operatively. Statistical analysis included paired *t*-tests and Pearson correlation.

Results:
Of the 28 patients who enrolled in the study and underwent bariatric surgery, 20 patients finished the study. Eighteen patients had fully completed all questionnaires. Mean age of this group was 45.3 years old (range 23–67), and mean preoperative body mass index (BMI) was 45.81 kg/m^2 (range 35.4–67.0). The mean post-operative BMI was 34.89 kg/m^2 (range 24.1–50.06) with mean decrease of 11.25 kg/m^2 after surgery (P<0.001, 95% CI: 8.9–13.6). The total mean preoperative PFDI-20 score was 71.06. The mean post-operative PFDI-20 score was 40.97. An overall improvement in symptoms were seen with a mean difference in overall symptom score of 30.09 after surgery (P<0.001 95% CI; 16.08–44.1). In two of the three subscales of the PFDI-20, Urinary Distress Inventory and Colorectal-Anal Distress Inventory, there was a significant decrease in symptom scores of 17.29 (P<0.001, 95% CI: 10.15–24.43) and 7.46 (P=0.017, 95% CI: 1.48–13.42) respectively. There was no significant change in overall Pelvic Organ Prolapse Distress Inventory in the PFDI-20. There was a significant reduction in total mean BESAQ score of 8.11 after surgery (P=0.002, 95% CI: 3.57–12.66), suggesting improved body image during sexual activity. Despite this, there was no change in mean total FSFI scores indicating a persistence of female sexual dysfunction.
Correlation analysis showed no association between BMI and change in BMI as it related to questionnaire data. Age and increased parity were negatively associated with desire scores on FSFI, but no other associations were seen. Age was also associated with higher overall post-operative PFDI-20 score.

Conclusions:
Bariatric surgery improves symptoms of pelvic floor dysfunction and body image during sexual activity 6 months after surgery. However, in this cohort sexual function was not significantly altered. Sexual function is complex and factors such as age and parity may make changes in weight negligible as a modifiable risk factor for sexual dysfunction.

References:
1. Richter HE, Burgio KL, Clements RH, Goode PS, Redden DT, and Varner RE. Urinary and Anal Incontinence in Morbidly Obese Women Considering Weight Loss Surgery. Obstet Gynecol 2005; 106: 1272–76.
2. Assimakopoulos K, Panayiotopoulos S, Iconomou G, Karaivazoglou K, Matzaroglou C, Vagenas K, Kalfarentzos F. Assessing Sexual Function in Obese Women Preparing for Bariatric Surgery. Obesity Surgery 2006; 16: 1087–1091.

Presentation Number: 78

BASELINE SEXUAL FUNCTION OF WOMEN SEEKING UROGYNECOLOGIC CARE

D. M. ELSER[1], E. STOCKWELL[2];
[1]Illinois Urogynecology, LTD, Oak Lawn, IL, [2]Illinois Urogynecology, Oak Lawn, IL.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To analyze the baseline data regarding sexual function in women seeking care in a urogynecology practice.

Background:
The prevalence of sexual satisfaction and dysfunction remains poorly understood. Urogynecologists are uniquely poised to study this aspect of a woman's life, as our interactions with our patients center around the most intimate of body functions and our surgical interventions for prolapse and incontinence may restore or diminish sexual health.

Methods:
Our Urogynecology practice routinely collects quality of life data on patients at baseline, and post surgery. The questionnaires include the Incontinence Impact Questionnaire (IIQ7) Pelvic Floor Distress Inventory (PFDI20), short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12), Urogynecology Network Sexual Function (UNSQ). In addition, our electronic medical record (EMR) allows women to respond to sexual function questions privately online prior to their visit. This work analyzes the baseline responses for new patients (NPs) seen in the latter half of 2009.

Results:
We identified 772 NPs seen in a private urogynecologic practice from June to December 2009, with a mean age of 56 (R17-94), mean parity of 2.2 (R0-14), & 57% menopausal. Age at first intercourse was a mean of 18 years (R13-25). Parity was not affected by age at 1st intercourse. Number of lifetime sexual partners ranged from 0 to 25, with 15% of patients virgins. By decile age, women currently is their 70's reported the most lifetime sexual partners, and those in their 50's, the fewest. Current sexual activity, sexual satisfaction and desire to discuss with MD are addressed in Table 1. Thirty percent of premenopausal women were not sexually active compared to 60% in the menopausal group. No patient over the age of 86 responded to, "do you want to discuss satisfaction with MD?. None over age 74 answered yes to that same question. Seventy percent of women with a new sexual partner in the previous 12 months were sexually satisfied, as opposed to 40% without new partner. (p= 0.04). Forty-five percent of women who were sexually satisfied wanted to discuss with MD in contrast to 60% of those who were not satisfied and did not want to discuss.(p=0.55) Sexual satisfaction did not differ between groups based on ability to orgasm. adequate lubrication, vaginal opening inadequate, experiencing dyspareunia, or dissatisfied due to physical changes. (p>.50). Table 2 describes the completion pattern for response to standardized quality of life questionnaires, the IIQ-7, PISQ-12, and PFDI-20.

Conclusions:
This data provides insight into baseline sexual function of women presenting to a Urogynecology practice. Only 13% of women did not answer the online question "are you sexually active", >60% did not answer the remainder of the sexual function questions, either online prior to the visit, or as a paper packet provided on the day of the visit. Interestingly, some patients responded selectively to certain QOL questions leaving others blank across the various instruments. Specific scores &responses for QOL instruments will be analyzed separately. It remains unknown why questions were left unanswered: because the women were seeking care for another problem, found the questions to be offensive, were intimidated to speak about personal sexual issues, the questionnaires were too long or other reasons.

References:
Sexual function in women: what is normal? Int Urogynecol J Pelvic Floor Dysfunct—01-MAY-2009; 20 Suppl 1: S9–17.
Sexual health in women with pelvic floor disorders: measuring the sexual activity and function with questionnaires—a summary. Int Urogynecol J Pelvic Floor Dysfunct—01-MAY-2009; 20 Suppl 1: S65–71.
Assessment of sexual function in women with pelvic floor dysfunction.—Int Urogynecol J Pelvic Floor Dysfunct - 01-MAY-2009; 20 Suppl 1: S45–50

Percent of women sexually active and satisfied

	no	yes	no response
Are you currently sexually active?	364 (51%)	257 (36%)	93 (13%)
Are you sexually satisfied?	140 (19.6%)	102 (14.3%)	472 (66.1%)
Want to discuss with MD?	183 (25.6%)	62 (8.7%)	469 (65.7%)

Percent response to standardized Quality of Life questionnaires

	did not respond	answered completed	answered selective questions
IIQ-7	63%	35%	2%
PISQ-12	61%	19%	13%
PFDI-20	68%	11%	28%
PFDI/POPDI	62%	26%	12%
PFDI/CRADI	62%	18%	20%

Presentation Number: 79

ONE YEAR OUTCOMES AND THE QUALITY OF LIFE OF ELDERLY WOMEN WITH PELVIC ORGAN PROLAPSE AFTER TENSION-FREE VAGINAL MESH (TVM) REPAIR

K. KATO[1], S. SUZUKI[1], S. YAMAMOTO[1], K. FURUHASHI[1], K. SUZUKI[1], T. MURASE[1], M. GOTOH[2];
[1]Japanese Red Cross Nagoya First Hosp., Nagoya, Japan, [2]Nagoya Univ., Nagoya, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to assess the impact of age on clinical outcomes and the quality of life (QOL) of the patients who underwent tension-free vaginal mesh (TVM) repair to treat pelvic organ prolapse (POP).

Background:
As the aging population is rapidly increasing in many countries, urgent demands for the POP treatment of elderly women have emerged. Transvaginal mesh repair is expected to be one surgical option suitable for the elderly due to its less invasiveness and effectiveness to improve QOL though there is criticism on mesh-related complications.

Methods:
Between 2006 and 2008, 505 consecutive women with POP quantification (POP-Q) stage III or IV underwent TVM repair. Afterwards they were stratified into three age groups; young (≤64 years, n=197), young-old (65–74 years, n=213), and old-old (≥75 years, n=95) group. TVM repair was performed by cutting polypropylene mesh (Gynemesh PS^{TM}) into a similar shape as Prolift™ and inserting their arms through the obturator foramen and sacrospinous ligament. Concomitant anti-incontinence procedures were avoided, and concomitant hysterectomy was restricted to 5 patients with cervical or ovarian pathology. POP-Q scale, prolapse-QOL questionnaire (P-QOL), international consultation on incontinence questionnaires short form (ICIQ-SF), and over-active bladder symptom score (OABSS) were assessed before and one year after operation in each age group. Statistical significance was determined using paired t-test or Wilcoxon's signed rank test.

Results:
The mean operative time was 52 min and mean intraoperative blood loss was 18 ml. Perioperative complications included 17 cases (3.4%) of bladder injury, and 1 case each consisting of rectal injury, blood loss over 200 ml, and temporary hydronephrosis. Residual urine during hospitalization remained over 50 ml in 25 patients (5.0%, ≤64: 4, 65–74: 16, ≥75: 5), but none required clean intermittent catheterization at home. Within 1-year follow-up, 8 patients (1.6%; ≤64: 3, 65–74: 3, ≥75: 2) had vaginal mesh exposure. These operative features and complications did not differ by age groups. POP-Q scores except tvl showed significant anatomical improvement in all age groups (Table 1). When prolapse recurrence is defined as POP-Q stage II or higher, 74 (37.6%) of ≤64 years group, 57 (26.8%) of 65–74 years group and 17 (17.9%) of ≥75 years group were classified as recurrence; younger group had more recurrence. However, vast majority of them were asymptomatic "point Aa failure" and only 5 cases (1.0%) necessitated re-intervention. A total of 36 patients (7.1%; ≤64: 12, 65–74: 16, ≥75: 8) required a second-stage midurethral slings due to persistent or de novo stress incontinence. All age groups showed significant postoperative improvements in QOL domains of P-QOL (Table 2). Prolapse and urinary symptom scores of P-QOL except stress urinary incontinence improved significantly in all age groups. ICIQ-SF and OABSS showed significant improvement of urinary incontinence and OAB, respectively (Table 3).

Conclusion:
Complications and outcomes of TVM repair did not differ significantly between age groups. Mesh exposure rate of 1.6% is low compared to other reports, which may be due to proper dissection layer and avoidance of concomitant hysterectomy. Although the percentage of "Aa point failure" was high (later dissection up to distal urethra and increasing mesh fixation points were useful to prevent distal retraction of the mesh), TVM repair markedly improved QOL, prolapse symptoms, OAB symptoms, and voiding symptoms. Treatment of prolapse with TVM technique seems to be a feasible and effective surgical option in the elderly population.

*Table 1 Changes in POP-Q score (cm) before and one year after the mesh repair. * Statistically significant differences between preoperative and post operative values (P< 0.0001)*

POP-Q point	≤64 years (SD)		65–74 years (SD)		≥75 years (SD)	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Aa	1.8 (0.9)	−1.2 (1.0)*	1.9 (.7)	−1.6 (1.0)*	1.9 (0.9)	−1.7 (1.2)*
Ap	0.5 (1.2)	−2.6 (0.7)*	0.4 (1.2)	−2.6 (0.7)*	0.5 (1.3)	−2.7 (0.9)*
C	2.1 (2.9)	−5.7 (2.5)*	1.9 (2.7)	−5.9 (2.4)*	2.7 (3.1)	−5.4(3.1)*
gh	4.8 (0.9)	3.9 (0.8)*	4.7 (0.9)	3.5 (0.8)*	4.6 (1.0)	3.3 (0.7)*

*Table 2 Changes in QOL domains of P-QOL before and 1 year after the mesh repair. * P< 0.0001, # P< 0.05*

	≤64 years (SD)		65–74 years (SD)		≥75 years (SD)	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
General health	53 (22)	28 (22)*	52 (21)	28 (21)*	55 (22)	36 (22)*
Prolapse impact	66 (28)	13(20)*	61 (29)	12 (20)*	60 (32)	14 (18)*
Role limitation	53 (31)	7 (16)*	51 (32)	8 (18)*	55 (35)	11 (17)*
Physical limitation	57 (31)	10 (18)*	58 (33)	11 (19)*	61 (33)	15 (25)*
Social limitation	26 (29)	3 (11) *	31 (32)	3 (12)*	37 (34)	6 (17)*
Personal relationship	28 (34)	9 (18)*	20 (28)	6 (18)*	12 (24)	2 (7) #
Emotion	56 (32)	11(20)*	56 (31)	10 (20)*	59 (36)	11 (20)*
Sleep energy	29 (26)	6 (13)*	31 (24)	5 (12)*	34 (29)	10 (20)*
Severity measures	51 (25)	8 (14) *	47 (25)	8 (15)*	44 (26)	8 (15)*

*Table 3 Changes in ICIQ-SF and OABSS before and one year after the mesh repair. *P< 0.0001*

	≤64 years (SD)		65–74 years (SD)		≥75 years (SD)	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
ICIQ-SF	4.6 (5.0)	2.7 (3.8)*	5.8 (5.2)	2.9 (3.7)*	6.8 (6.2)	3.2 (4.2)*
OABSS	3.8 (2.9)	2.0 (2.4) *	5.0 (3.3)	2.4 (2.5)*	6.3 (3.7)	2.7 (2.8)*

Presentation Number: 80

THE EFFECT OF UTERINE FIBROID EMBOLIZATION ON LOWER URINARY TRACT SYMPTOMS

D. SHVEIKY[1], C. B. IGLESIA[1], D. D. MARSHALL[1], B. I. KUDISH[1], J. LEE[2], M. JONES[2], J. L. PETERSON[1], J. L. PETERSON[1], J. HUANG[3], J. B. SPIES[2];
[1]Washington Hosp. Ctr./Georgetown Univ. Med. Ctr., Washington, DC, [2]Georgetown Univ. Hosp., Washington, DC, [3]Medstar Res. Inst., Washington, DC.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To determine the effect of uterine fibroid embolization (UFE) on lower urinary tract symptoms (LUTS) and quality of life (QoL).
Materials and Methods:
This prospective study included women with symptomatic fibroid uterus who had LUTS and underwent UFE between 3/2008 and 5/2010. All subjects underwent a pre-procedure pelvic MRI and completed the patient centered goals assessment, Urinary Distress Inventory (UDI-6), Urinary Impact (IIQ-7), PISQ-12, Uterine Fibroid Symptom (UFS-QoL) and standardized 48 h bladder diary preoperatively and 3 months after the procedure. Patient Global Impression of Improvement (PGI-I) was used to assess patient satisfaction. The primary outcome was the measure of subjective improvement in LUTS at 3 months after intervention as measured by a decrease in the Urinary Distress Inventory (UDI-6). Univariate analysis, paired t-test and a stepwise regression analysis were utilized as required.
Results:
Fiftty six patients underwent UFE and completed the 3 months questionnaires. Patients' characteristics are summarized in Table 1. At 3 months after UFE, patients had a significant decrease in UDI-6, IIQ-7 and fibroid symptoms scores, indicating an improvement in urinary symptoms and QoL (Table 2). Bladder diaries showed a significant reduction in total voids at day and night. No difference was found in incontinence episodes, stress incontinence or urge incontinence scores before and after the procedure. Uterine volume, dominant fibroid size, location or bladder compression did not affect the difference in UDI-6 scores. In a stepwise regression model, BMI had a significant impact on UDI-6 score difference, with a decrease of the difference by 1.18 points for each 1 unit increase in BMI.
Conclusion:
UFE significantly improves LUTS and urinary related QoL with no effect on incontinence. Obesity seems to attenuate this effect.

Table 1: Patient Characteristics

Mean age (yr)	44.1
Mean BMI	29.8
Median parity (range)	1 (0–5)
Race (%): African American	69.6
White	21.8
Hispanic	4.3
Asian	4.3
Previous myomectomy (%)	23.9
Mean Uterine volume (cm^3)	735.1
Mean dominant fibroid volume (cm^3)	379.73
Fibroid type (%):	
Submucosal	4.35
Intramural	73.91
Subserosal	21.74
Dominant fibroid location (%):	
Anterior	41.9
Posterior	34.9
Lateral	23.2
Dominant fibroid location (%):	
Fundal	34.9
Corporeal	55.8
Cervical	9.3
Bladder compression (%)	17.8

Table 2: Post-procedure subjective change in symptoms

	Preop	Postop	Difference	P-value
Total voids	9.07	6.43	−2.65	<0.0001
Voids at daytime	7.68	5.89	−1.8	<0.0001
Voids at night	1.26	0.61	−0.65	0.0012
# of accidents	0.50	0.38	−0.122	0.57
UDI-6 score	44.70	21.37	−23.33	<0.0001
UDI-6 UUI	0.565	0.413	−0.15	0.13
UDI-6 SUI	0.565	0.500	−0.065	0.55
UDI-6 Incomplete emptying	0.370	0.326	−0.043	0.68
IIQ-7 score	**21.42**	**6.40**	**−15.02**	**<0.0001**
PISQ	35.15	37.70	2.55	0.0018
Fibroid score total	119.49	71.96	−47.53	<0.0001

Presentation Number: 81
ASSESSMENT OF QUALITY OF LIFE OF PATIENTS SUPPORTED FOR GENITAL PROLAPSE SURGERY: FEASIBILITY OF A COMPUTERIZED DATA COLLECTION
V. LETOUZEY, S. HUBERLANT, P. MARES, R. DE TAYRAC; CHU Caremeau, Nimes, France.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To compare the performance in terms of filling of a fill mode terminal computerized touch screen questionnaires to a paper mode, for assessing symptoms (PISQ-12, PFDI-20) and quality life (PFIQ-7) of patients with pelvic floor disorders scheduled for surgery.
Background:
Pelvic organ prolapse (POP) is an anatomical entity supported for its functional impact. It is therefore necessary to assess this impact (symptoms and quality of life). This assessment is necessary to judge the quality of care and surgical indication.
The questionnaires to be more objective are self questionnaires, however they were failing to require patients' motivation to fill them. The ease of completing and integrating them into the management of prolapse is key to their wider dissemination in clinical practice.
Methods:
This prospective study was a randomized control trial, performed for 12 months. Inclusion criteria relate to patients consulting for a pelvic floor disorder requiring surgery.

The self-questionnaires are validated in French (short versions of PFDI-20 [pelvic floor distress inventory], the PFIQ-7 [pelvic floor impact questionnaire]) and PISQ 12 [questionnaire on sexuality]. They aim to assess the quality of life of patients suffering from a disorder of the pelvic floor (pelvic organ prolapse and/or urinary incontinence). Patients do not speak the French language are excluded from the study.

PISQ-12 was considered as complete with a maximum of 2 responses not completed. PFDI 20 and PFIQ 7 were considered complete if all questions (100%) were completed.

Patients are being offered, randomized either a paper questionnaire at the preoperative consultation and then a computerized questionnaire, the day before surgery, or the reverse. Both episodes must be between 2 weeks and a month.

Touch screen computer is an alternative computer paper questionnaires. The computerized version of self-validated questionnaires following (PISQ-12, PFDI-20, PFIQ-7) was integrated into a software manager, calculating scores immediatly.

The results in tables used for data collection are the average time to fill questionnaires. The fill rate was defined by the number of completed questionnaires per patients included, it means the all 3 (or 2, without sexual activities) questionnaires.

The study benefits of an institutional review board agreement.

Results:

29 patients suffering from pelvic floor disorders requiring surgery were randomized. The average patient age was 68 years. The matching criteria such as age, parity, sexuality and prolapse history did not show differences between the two groups. The average delay before two questionnaires was 3 weeks (+/−0.3)

The time of patients inclusion corresponds to the pre-operative visit with the surgeon and patients were randomized into 2 groups: 15 patients have integrated the group “Computer - Paper” group and 14 patients“ Paper - Computer ”.

The average time to fill out questionnaires “computer” is 16 min (+/−4) against 22 min (+/−5) for the “paper” questionnaire ($p<.05$).

The filling of self-validated questionnaires by computer via a touch screen terminal provides a better fill rate (61.6%=% of patients with completely filled questionnaires) that the award as a classic paper (51%) (p< .05).

Fill rates are higher in ‘computing’ for the questionnaire PFDI-20 65% ($n=19/29$) of patients completed the computer questionnaire against 48% ($n=18$) for the questionnaires PFDI-20 “paper” ($p<.05$). 58% ($n=11/19$) of patients completed the questionnaire PISQ-12 with the computerized version against 31% ($n=9$) for the computer questionnaire PISQ-12 ($p<.05$).

Finally, there is no significant difference in filling the questionnaire PFIQ-7 with a fill rate in 2 homogeneous groups of 62% ($n=18/29$) ($p>.05$).

Conclusions:

Access to self-administered questionnaire on a touch screen terminal would have a best fill rate (61.9%) than the conventional paper form (51%). In addition it appears that a gain of filling time is observed with the computer questionnaires.

Such data collection could help to optimize the surgical management of patients suffering from pelvic floor disorders with a better distribution of the questionnaires.

Presentation Number: 82

MORBI-MORTALITY REGISTRY AFTER POP SURGICAL TREATMENT AMONG FRENCH GYNECOLOGIST SURGEONS. PRELIMINARY RESULTS ON THE FIRST 1107 PROCEDURES

R. DE TAYRAC[1], G. EGLIN[2], P. DEBODINANCE[3], T. PEREZ[4], J. MARTY[5], J. L. FAILLIE[1], B. JACQUETIN[6];
[1]Caremeau Univ. Hosp., Nîmes, France, [2]Champeau Private Hosp., Béziers, France, [3]Gen. Hosp., Dunkerque, France, [4]Gen. Hosp., Aubagne, France, [5]Gynerisq Organisation, Paris, France, [6]Estaing Univ. Hosp., Clermont-Ferrand, France.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The main objective of this study was to evaluate morbidity after POP surgical treatment, involving all surgical techniques, in both private and public French hospitals during 1 year. The secondary objective was to describe current surgical practice, including vaginal mesh surgery, among French Gynecologist surgeons.

Background:

If many surgical techniques for POP reconstructive surgery have been described, robust comparative data between abdominal and vaginal surgery are still lacking. Furthermore, comparative studies, even randomized controlled trials, are not always transposable to clinical practice. Registries are of great interest for clinical practice.

Methods:

A web-registry on POP surgical treatment was put online in may 2010. That registry was included in the Gynerisq website, mainly available for physicians practicing private Obstetrics and Gynecology, but also open to public hospitals. To motivate physicians, declarations were followed by a reduced rate of insurances. Inclusions are still ongoing and follow-up of 1-year is scheduled. That registry obtained the required acceptance of the National Commission of Informatics and Liberty (CNIL), the French Health Authority (HAS) and the French College of Obstetrician and Gynecologist (CNGOF).

Results:

During 9 months (May 2010–January 2011), 1107 surgical procedures were recorded among 193 surgeons. Nine-hundred and twenty-two procedures were done vaginally (83.3%) versus 185 abdominally.

Among abdominal procedures, 157 (84.9%) were done laparoscopically, including 10/157 assisted robotic procedures (6.4%). Technically, polypropylene meshes were preferred to polyester in 69.7%, sutures were preferred to staples in 88.7% and a posterior mesh fixed on the levator ani muscles were associated in 77.3% of cases. Associated hysterectomy and SUI surgical treatment were done in 23.2% and 15.7%, respectively.

Among vaginal procedures, 749 anterior repairs, 500 apical suspensions, and 414 posterior repairs were recorded. Synthetic meshes were used in 438 (58.5%) anterior repair and 177 (42.8%) posterior repair. The transobturator technique was preferred for anterior mesh in 86% of cases (377/438). Apical suspensions were done by sacrospinous suspension, posterior tape and high

uterosacral ligament fixation in 48.6%, 34.8% and 16.2%, respectively.

Intra-operative and post-operative complications are summarized in Tables 1 and 2.

The rate of reoperation was 2.4% vs 4.9% after vaginal and abdominal surgery, respectively (p=0.08).

Table 1. Intra-operative complications occurred in 54/1107 patients (4.9%).

	Vaginal Surgery *n=922*	***Abdominal Surgery*** *n=185*	*p*
Overall intraop complications	40 (4.3)	14 (7.6)	*0.06*
Major complications	**22 (2.4)**	**7 (3.8)**	
Bladder injuries	10 (1.1)	2 (1.1)	*1*
Rectal injuries	4 (0.4)	2 (1.1)	*0.3*
Vascular injuries	1 (0.1)	2 (1.1)	*0.07*
Hemorrhage	7 (0.8)	1 (0.5)	*1*

n(%)

Table 2. Post-operative complications, with a follow-up up to 9 months, occurred in 279/1107 patients (25.2%).

	Vaginal Surgery *n=922*	***Abdominal Surgery*** *n=185*	*p*
Overall postop complications	228 (24.7%)	51 (27.6%)	*0.4*
Major complications	**47 (5.1)**	**22 (11.9)**	
Hematomas	19 (2.1)	3 (1.6)	*0.2*
Vaginal erosions	13 (1.4)	4 (2.2)	*0.5*
Chronic pains	8 (0.9)	5 (2.7)	*0.05*
Bowel occlusions	0	5 (2.7)	*<.0001*
Pelvic abscess	0	1 (0.5)	
Neuralgia	1 (0.1)	1 (0.5)	
Fistula	5 (0.5)	1 (0.5)	
Spondylodicitis	0	1 (0.5)	
Pulmonary embolism	0	1 (0.5)	
Death	1 (0.1)	0	

n(%)

Conclusions:

Morbi-mortality could occur after both vaginal and abdominal reconstructive surgery for POP. The knowledge of complication rates in routine surgical practice is important for preoperative inform consent.

Presentation Number: 83

RISK FACTORS FOR EXPOSURE AFTER TENSION-FREE VAGINAL MESH PROCEDURE

M. I. WITHAGEN[1], M. E. VIERHOUT[1], K. B. KLUIVERS[1], A. L. MILANI[2];

[1]Radboud Univ. Nijmegen Med. Ctr., Nijmegen, Netherlands, [2]Reinier de Graaf Group, Delft, Netherlands.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

The objective of this study was to identify the risk factors for mesh exposure at 12 months following implantation of tension-free vaginal mesh for pelvic organ prolapse (POP) in a large cohort study.

Background:

Mesh exposure is the most typical and most common reported complication associated with the use of mesh in POP surgery. Exposures have been reported as early as 6 weeks and late as 4 years after vaginal mesh surgery, but usually occur during the first year following the intervention (1).

Methods:

A prospective observational cohort study was performed in two centers. Patients with a recurrent POP stage ≥ II and patients with a primary POP stage ≥ III who, after counseling opted for mesh-surgery (Prolift) were included in this study. Evaluation at baseline, 6 weeks, 6 months and 12 months included Pelvic Organ Prolapse Quantification (POP-Q), symptom assessment (with a validated questionnaire) and complication assessment. Univariable logistic regression was used to study the influence of the possible risk factors. Multivariable logistic regression with forward selection procedure was used to indicate those variables that are independently related to predict mesh exposure. Variables reaching statistical significance at the $p<0.10$ level in the univariable analysis were valid for entry model in the selection procedure. The adjusted odds ratios with 95% confidence interval of the final model are presented. A p-value below 0.05 was considered statistically significant. Statistical analysis was performed using SPSS 15.0 for Windows (SPSS inc., Chicago, Ill., USA).

Results:

Three hundred and seventy-four women met the inclusion criteria. Twelve months follow-up data were available on 294 patients (79%). Data are presented in table 1, 2 and 3.

Table 1. Baseline characteristics

Variable	(n=294)
Age, mean (SD), years	63.7 (12.1)
BMI, mean (SD), kg/m^2	25.9 (3.4)
Menopause, No. (%)	248 (84)
Parity, median (range)	2 (0–7)
Previous POP repair, No. (%)	188 (64)
Current smoking, No. (%)	30 (10)
Diabetes Mellitus, No (%)	9 (3)
Pelvic organ prolapse	
- stage II	98 (33)
- stage III	185 (63)
- stage IV	11 (4)
Pre-operative pain, No. (%)	62/252 (25)
Pre-operative sexually active, No. (%)	140 (48)
Pre-operative dyspareunia, No. (%)	60/140 (43)
Pre-operative not sexually active due to dyspareunia, No. (%)	12/98 (12)

Table 2. Data at 12 months

Variable	(*n*=294)
POP stage in mesh-treated compartment	
- stage 0	188 (64)
- stage I	68 (23)
- stage II	36 (12)
- stage III	2 (1)
- stage IV	0
Exposure within 12 months, No. (%)	34(12)
Post-operative pain, No. (%)	35/275 (13)
Post-operative sexually active, No. (%)	171 (58)
Post-operative dyspareunia, No. (%)	77/171 (45)

Table 3. Factors associated to mesh exposure.

Factor	Univariable		Multivariable *n*=268
	n		
Age (years)	294	**.97(.94–.99)**	.97(.93–1.01)
Menopause (y/n)	269	2.1 (.66–6.73)	
Previous POP repair (y/n)	287	1.83 (.79–4.20)	
Smoking (y/n)	286	**4.1 (1.71–10.06)**	**3.08(1.09–8.72)**
Diabetes (y/n)	294	.96 (.12–7.88)	
Parity (n)	268	1.01(.74–1.39)	
POP-stage	294		
- stage II		ref	
- stage III		1.81(.22–15.18)	
- stage IV		1.08(.13–8.91)	
PO Sexually active (y/n)	276	**2.08(.90–4.79)**	2.15(.79–5.79)
Body Mass Index (kg/m^2)	290	1.03(.93–1.14)	
Location Prolift			
- anterior (y/n)	294	**.49(.22–1.11)**	not selected
- posterior (y/n)	294	.75(.37–1.54)	
- Ant + pos(y/n)	294	.67(.23–2.01)	
- Total (y/n)	294	**2.42(1.14–5.14)**	**2.95(1.24–7.01)**
Prolift combined (y/n)	294	.99(.43–2.29)	
Op. time (per 20 min)	283	1.22(.91–1.65)	
Blood loss (per 100 ml)	278	1.14(.93–1.39)	
Any complication (y/n)	294	1.47(.65–3.35)	
Failure (y/n)	294	**.18(.024–1.38)**	.20(.025–1.54)
Bladder injury (y/n)	294	1.28(.15–10.95)	
PO hematoma (y/n)	294	1.56(.33–7.45)	
Re-intervention (y/n)	294	3.91(.35–44.3)	
Surgeon	294		
- surgeon A		ref	not selected
- surgeon B		.87(.34–2.25)	
- surgeon C		**3.89(1.30–11.62)**	
- surgeon D		2.19(.82–5.89)	
Experience (per 10 years)	294	**.55(.34–.89)**	**.49(.29–.83)**
Number of Prolift (per 10)	294	.95(.87–1.03)	
Pain before (y/n)	252	.84(.34–2.05)	
Dyspareunia before (y/n)	160	.85(.35–2.08)	

Conclusions:
This study clearly demonstrated that smoking, total Prolift and less surgical experience were independent risk factors for mesh exposure after a tension-free vaginal mesh procedure.
References (optional):
(1) Am J Obstet Gynecol. 2010 Sep; 203(3):235.e1–8.

Presentation Number: 84

PREVALENCE AND OUTCOME OF URINARY RETENTION AFTER LAPAROSCOPIC SURGERY FOR SEVERE ENDOMETRIOSIS—DOES HISTOLOGY PROVIDE ANSWERS ?

B. GABRIEL[1], J. NASSIF[2], A. LIMA[3], S. BARATA[3], G. LANG-AVÉROUS[3], A. WATTIEZ[3];
[1]Freiburg Univ. Hosp., Freiburg, Germany, [2]American Hosp. of Beirut, Beirut, Lebanon, [3]Strasbourg Univ. Hosp. Hautepierre and CMCO, Strasbourg, France.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, partial funding
Work supported by industry: No

Objective:
Our study purpose was to evaluate the prevalence of postoperative urinary retention after radical laparoscopic surgery for severe endometriosis and to analyze the clinical outcome of these patients. Furthermore, we aimed to investigate the staining pattern of nerve fibers and ganglion cells in the resected specimens and to compare these findings with a group of matched control patients without urinary retention. We were also interested in identifying patients at risk for a long-term persistence of urinary retention.
Background:
Urinary retention after radical laparoscopic surgery for severe endometriosis is a clinically relevant complication, which clearly limits the quality of life of the affected, mostly young women. Data on the prevalence and the clinical outcome are scarce. Nerve-sparing surgery is believed to be protective. Consequently, it would be tempting to speculate on differences in the quantity of autonomic nerves in the resected specimens when comparing women with and without postoperative urinary retention in order to characterize candidates being at risk for this complication.
Methods:
Two hundred twenty one patients undergoing surgery between July 2007 and February 2010 were eligible for this single center, retrospective case series. The inclusion criterion was presence of postoperative urinary retention. The expression of autonomic nerves in the resected specimens was investigated in patients with urinary retention and matched control patients without this condition. Immunohistochemistry analysis was performed according to a standardized technique using the monoclonal anti-Protein S100 antibody.
Results:
The prevalence of urinary retention was 4.6%. Unilateral resection of endometriotic nodules did not preclude the occurance of this complication. Importantly, there was no

difference between cases and controls with regard to the quantity of autonomic nerves in the resected specimens ($p > 0.05$). Sixty percent of patients had a persistence of urinary retention for several months and according to the Kaplan-Meier analysis, the 50% probability to overcome urinary retention was achieved after 5.6 months (Figure 1). Age was a major risk factor for a persistent urinary retention.

Conclusion:

In older endometriosis patients, surgical radicality should be balanced against preservation of organ function. There is still a fairly good chance for recovery from urinary retention, even after a 6–8 months interval, which is important for patient counseling. We discuss potential operative strategies to avoid this complication.

Presentation Number: 85

PERCUTANEOUS NERVE EVALUATION (PNE): LESSONS LEARNED

M. A. CRITES, M. MUKATI, A. SORIAL, G. GHONIEM; Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

The primary aim of this study is to identify risk factors affecting efficacy and response to office-based percutaneous nerve evaluation (PNE). Secondarily, we aim to identify appropriate candidates to undergo office-based PNE.

Background:

PNE is considered the primary step to evaluate response to neuromodulation for patients with voiding dysfunction. If successful, patients then undergo permanent sacral nerve root lead implantation. Given the simplicity of procedure performance and the need for very little anesthesia, many surgeons are electing to perform office-based PNE with local anesthesia and/or oral sedation given prior to the procedure. The challenge remains to determine the most appropriate candidates to undergo office-based PNE so as to maximize efficacy and patient success. Through this study, we determined risk factors to guide selection of the most appropriate candidates to undergo office-based sacral neuromodulation trial.

Methods:

A retrospective chart review was conducted from 2000 to 2010 of all patients who underwent PNE in the office-based setting. Data was separated into three groups based on PNE outcomes: Success, equivocal, and failure. Data examined included patient demographics, voiding dysfunction diagnosis, comorbidities, evidence of previous pelvic nerve injury, body mass index (BMI), and hormonal status. BMI was analyzed as a risk factor separately by categorized according to World Health Organization 2011 weight classifications: BMI 18.50–24.99 (normal), BMI 25.0–29.99 (overweight), and BMI >30 (obese). All data were analyzed using chi-square analysis and ANOVA. A p-value <0.05 was considered statistically significant.

Results:

One hundred and twelve females (112) underwent office-based PNE. Seventy-four (66.1%) patients had a successful outcome, 15 (13.4%) had an equivocal outcome, and 23 (20.5%) patients failed PNE trial. Table I illustrates factors analyzed for unfavorable PNE outcome. Neurological injury was the only factor found to be the most likely negative contributing factor for an unsuccessful trial of office-based PNE. After categorizing BMI, no significance was found for BMI as a risk factor for unfavorable PNE outcome.

Table I. Predictors of Unfavorable PNE Outcome

Factors	Success	Equivocal	Failure	p-value
Menopause	61 (55%)	11 (10%)	22 (20%)	ns
Systemic Hormones	32 (29%)	5 (5%)	6 (5%)	ns
PPS	43 (38%)	11 (10%)	12 (11%)	ns
DM	11 (10%)	2 (2%)	4 (4%)	ns
Smoking	5 (5%)	0 (0%)	3 (3%)	ns
NI	18 (16%)	7 (6%)	16 (14%)	**0.00**
Frequency	70 (63%)	13 (12%)	23 (18%)	ns
Urgency	73 (65%)	13 (12%)	22 (20%)	ns
Nocturia	68 (61%)	13 (12%)	22 (20%)	ns
UUI	68 (61%)	12 (11%)	18 (16%)	ns
UR	3 (3%)	2 (2%)	4 (4%)	ns

Conclusion:

Our cohort demonstrates neurological injury to be a predictive factor that predisposes patients to an equivocal or failed outcome of office-based PNE trial. Patients with this risk factor who are considered appropriate candidates for neuromodulation trial should undergo staged implantation with tined-lead in the operating room to provide these patients with the greatest opportunity for successful outcome.

Presentation Number: 86

NEW TEST FOR THE DIAGNOSIS AND QUANTIFICATION OF OBSTRUCTIVE DEFECATION SEVERITY IN WOMEN

A. M. PEREDA[1], J. MARCO[2], M. ESPUÑA[3], S. CASAS[4], M. GIRVENT[1], C. GÓMEZ[1], G. DEL REAL[1], V. ÁLVAREZ[1], F. OJEDA[1];
[1]Hosp. Gen. de Granollers. Univ.t Internacional de Catalunya, Barcelona, Spain, [2]Basic Psychology Dept.. Univ.t de Barcelona, Barcelona, Spain, [3]Hosp. Clínic. Univ.t de Barcelona, Barcelona, Spain, [4]Hosp. de la Creu Roja, Barcelona, Spain.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of the present study was to present a simplified and validated test based on the Rome III criteria[1], to diagnose and quantify the severity of obstructive defecation in women.

Background:
Constipation is a subjective symptom with a rough prevalence of 14%. Half of constipated patients suffer from obstructive defecation. Recently, an international group has standardized its diagnosis criteria in a document called Rome III criteria. But there is no validated and specific test for obstructive defecation that can measure de severity of this pathology[2].
Methods:
Three tests were developed. The Rome III test based in the Rome III criteria (gold standard), a quality of live questionnaire (subjective feeling of constipation) and third a new 8-item test.
A hundred and fifty patients recruited from uro-gynecological outpatient clinic of Fundació-Hospital Asil of Granollers Hospital completed the three tests.
The internal analysis was performed using PASW 18
Results:
The internal analysis of the 8-items test determined that 3 of the 8 items explained 74'11% of test variance. These three questions were selected to create the new questionnaire: the obstructive defecation test (ODT). The statistical correlation between ODT and Rome III test was 0'96.
The ODT internal consistency (reliability) yielded a Cronbach's alpha coefficient of 0'79. The Cohen's Kappa coefficient revealed a validity value of 0'94 between ODT and Rome III test. ROC curves with Rome III test (objective reality) presented an area under the curve of 0'99 and with the quality of life test (subjective reality) presented a 0'95 value. The ODT score for quantifying constipation severity ranged from 0 to 13. Using the values of the quality of life test, we established ranges of severity based on ODT scores: normal (>3), mild-moderate (3–7) and severe (8–13).
Conclusions:
Present results suggest that the new ODT might quantify the severity of obstructive defecation in women and might be a feasible test for the diagnosis and follow-up of this pathology.
References:
1. Rome III: The Functional Gastrointestinal Disorders, 3rd Edition. McLean, VA: Degnon Associates, 2006;1–1048.
2. Set-up and statistical validation of a new scoring system for obstructed defaecation syndrome. Ltd. Colorectal Disease 2007

Presentation Number: 87
THE EFFECT OF POSTERIOR COLPORRHAPHY ON ANORECTAL FUNCTION
A. DUA[1], S. C. RADLEY[1], G. L. JONES[2], S. JHA[1], S. BROWN[1];
[1]Sheffield Teaching Hosp. NHS Fndn. Trust, Sheffiled, United Kingdom, [2]Sheffield Univ., Sheffiled, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To determine the effect of posterior colporrhaphy on bowel symptoms using prospectively collected questionnaire data.

Background:
Posterior vaginal prolapse is often associated with bowel dysfunction and faecal incontinence. The relationship between different symptoms is complex and conditions may be causally related or coexist independently. Surgery for prolapse of the posterior compartment commonly involves colporrhaphy, aiming to achieve anatomical correction and improved function. However, evidence relating to the impact of posterior colporrhaphy on functional bowel symptoms is limited (1).
Methods:
This study was conducted in a tertiary referral urogynaecology unit in the UK with local research ethics committee approval. The electronic pelvic floor symptoms assessment questionnaire (ePAQ) is completed by women attending urogynaecology clinic as part of their routine care, on initial assessment and at post-operative follow-up. The bowel dimension of ePAQ automatically computes domain scores for IBS, constipation, evacuation, continence and quality of life on a scale of 0–100 (0 = best possible, 100 = worst possible health status). Data were collected prospectively for women undergoing rectocoele repair between 2008 and 2010. ePAQ was completed both pre and 3–6 months post-operatively. Only women who gave consent for use of their data were included in the analysis (n=60). Preoperative bowel domain scores (IBS, constipation, evacuation, continence & QoL) were compared with postoperative scores (Student t test). Individual symptoms were compared using Wilcoxon signed rank test.
Results:
Data from 60 women undergoing posterior colporrhaphy were analysed. Significant improvement (student t test: $p<0.05$) was observed in domain scores for bowel evacuation (42%), continence (37%) and bowel related quality of life (61%). IBS improved by 28% though this did not reach significance ($p=0.06$). There was no change noted in the scores for constipation ($p=0.98$) (Table 1). All individual symptoms relating to bowel evacuation and continence were improved significantly except painful evacuation, incontinence to solid stool and incontinence without reason, with substantial improvement noted in perineal splinting and incontinence to liquid stools (Wilcoxon signed rank test, $p<0.05$).
Conclusion:
Bowel evacuation and continence are significantly improved 3–6 months following posterior repair and are associated with parallel improvement in health related QoL.
References:
1. Obstet Gynecol 2004;104:1403–21.

Table 1: Change in ePAQ domain scores for bowel function following posterior repair

Domain	Mean pre-op score	Mean post-op score	t-test
IBS	23.9	17.2	0.066
Constipation	18.7	18.6	0.98
Evacuation	27.6	16.1	0.001
Continence	13.7	8.6	0.035
Bowel QoL	18.7	7.2	0.002

Presentation Number: 088

PROSPECTIVE-RANDOMIZED STUDY COMPARING HIGH UTEROSACRAL VAULT SUSPENSION VS. ABDOMINAL SACRAL COLPOPEXY FOR THE CORRECTION OF APICAL DEFECTS AND VAGINAL VAULT PROLAPSE

C. RONDINI[1], H. F. BRAUN[1], J. ALVAREZ[2], M. URZUA[2], R. VILLEGAS[2], M. ESCOBAR[2], S. AROS[2], C. WENZEL[3], C. DESCOUVIERES[3];
[1]UGCM&RN Hosp. Padre Hurtado, Facultad de Med. Univ. del Desarrollo Clinica Alemana/Clinica Santa Maria, Santiago, Chile, [2]UGCM&RN Hosp. Padre Hurtado, Facultad de Med. Univ. del Desarrollo Clinica Alemana, Santiago, Chile, [3]Clinica Alemana, Santiago, Chile.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To compare surgical objective and subjective success between abdominal sacral colpopexy (SCP) and high uterosacral vault suspension (HUVS) at 12 months follow up.

Methods:
Patient consent and ethical approval were obtained. We ran a prospective randomized study to demonstrate a 20% difference in cure rates between two surgical techniques (HUVS & SCP) in patients with a severe apical defect defined as POP Q point C ≥ stage 3. The number of patients needed to demonstrate this difference with a significance of $p=0.05$ and a power of 80% was 124. The primary outcome was to evaluate surgical objective success defined as POP Q point C < stage 2.
PFDI-20, P-QOL and PISQ-12 were used for subjective assessment of quality of life (QOL) and treatment success. Secondary objectives were to compare surgical time, intra and post surgical complications, hospital stay and anterior or posterior compartment relapse between both surgical techniques. Objective success is shown as survival curves using the Kaplan Meier method

Results:
Of 124 patients, 63 were randomized to SCP and 61 to HUVS. After randomization process 9 and 5 patients respectively declined surgery for different reasons. Finally 54 patients who underwent SCP and 56 who underwent HUVS were compared with a mean follow up of 12 months. Both groups had similar epidemiologic features (Table#1).

Table 1. Epidemiologic features of SCP and HUVS

Epidemiologic factor	SCP	HUVS	p
Age	**57.8±9.7**	**57.1±9.9**	**0.68**
Parity	**3,6 ±1.7**	**3,8±1.8**	**0.54**
Body Mass Index	**28.9 ±3.7**	**30.3±5.5**	**0.08**
Previous POP Surgery	**11.1%**	**7.1%**	**0.46**
Previous Hysterectomy	**25.9%**	**17.9%**	**0.30**
Stage 4 POP-Q	**22.2%**	**25.0%**	**0.73**

The Impact of a symptomatic prolapse, quality of life and sexuality before the surgery were similar in both groups (Table 2).

Table 2: Pre operative questionnaires scores for SCP and HUVS

Questionnaire	SCP	HUVS	p
PFDI - 20	104.0	109.2	0.831
P-QOL	457.4	589.0	0.189
PISQ-12	25.0	28.0	0.400

The objective success rate for apical suspension at 12 months follow up was 100% for SCP and 82.5% for HUVS (log rank p 0.033). SCP and HUVS produced a significant subjective improvement when we compared pre and post operatory POP symptoms, Quality of life and Sexuality scores (Table 3 and 4).

Table 3: Subjective success in SCP Group.

Questionnaire	Preoperative	Postoperative	p
PFDI - 20	104.0	20.3	0.011
P-QOL	457.4	109.0	0.001
PISQ-12	25.0	29.7	0.222

Table 4: Subjective success in HUVS Group.

Questionnaire	Pre-operatory	Post-operatory	p
PFDI - 20	109.2	31.0	0.001
P-QOL	589.0	96.6	0.001
PISQ-12	28.0	33.4	0.027

There were no subjective differences in both groups (Table 5).

Table 5: Post operative questionnaires scores for SCP and HUVS

Questionnaire	SCP	HUVS	p
PFDI - 20	20.33	31.0	0.457
P-QOL	109.0	96.6	0.860
PISQ-12	29.7	33.4	0.195

The failure in the anterior and posterior compartment defined as POP Q Ba and Bp points ≥ stage 3 at 12 months was 5.3% for SCP vs 33.3% for HUVS ($p<0.001$) and 0% for SCP vs 6.2% for HUVS ($p=0.035$). Further prolapse surgery of any compartment was required in 5.6% vs 17.9% of patients in each group ($p=0.043$). Hospital stay and surgical times were significantly lower in the HUVS group: 3.7±0.5, vs 2.1±0.7 days $p<0,001$ and 102.4+27 vs 80.3+24 min $p<0.001$. Intraoperative complication rates were 3.7% for SCP v/s 0.0% for HUVS ($p=0.146$). Postoperative complications were 20.4% for SCP and 7.3% for HUVS ($p=0.047$).

Conclusions:
SCP has statistically significant lower objective failure rates than HUVS for the correction of apical defects as well as the anterior and posterior compartments. Both techniques showed a significant

improvement in preoperative pelvic organ prolapse symptoms, quality of life and sexuality with no significant differences between both surgical procedures.

Presentation Number: 089

EVALUATION OF TRANSOBTURATOR TAPES IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE WITH VERSUS WITHOUT CONCOMITANT PROLAPSE REPAIR AT 1 YEAR FOLLOW-UP

M. ABDE-FATTAH[1], D. AYANSINA[1], I. RAMSAY[2], S. PRINGLE[3], C. HARDWICK[3], S. BJORNSSON[3], A. MOSTAFA[1], H. ALI[3];
[1]Univ. of Aberdeen, Aberdeen, United Kingdom, [2]Forth Vally NHS, STIRLING, United Kingdom, [3]Greater Glasgow & Clyde, Glasgow, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To assess the efficacy of transobturator tension-free vaginal tapes (TO-TVT) in the management of symptomatic female stress urinary incontinence (SUI) when associated with concomitant pelvic organ prolapse (POP) repair as regards:
-Patient reported & objective cure rates at 12 month.
-Quality of life and Sexual function.

Background:
The efficacy of continence surgery with concomitant prolapse repair has been controversial. The "James Lind Alliance"[1], a multi-disciplinary group of urologists, gynaecologists, academics, patients support groups representatives and scientific societies (such as British Society of Urogynaecologists and British Association of Urological surgeons) has recently highlighted surgical treatment of SUI at the time of concomitant prolapse repair as one of the top 10 research priority areas in urogynaecology.

Patients and Methods:
A prospective study of 133 women who underwent TO-TVT with concomitant POP repair in the period between April2005 and April2007 (study group). Outcomes were compared to 299 women who underwent TO-TVT as a sole procedure in the same time period within the same institution with the same inclusion and exclusion criteria (control group). The inclusion criteria included women with failed or declined pelvic floor muscle training (PFMT), pre-operative urodynamic SUI or mixed incontinence (MUI) with predominantly bothersome SUI symptoms (self-reported), symptomatic prolapse and SUI. Pre-operative assessment included: urodynamic assessment, completion of validated symptom severity and quality of life (QOL) questionnaires; King's Health Questionnaire (KHQ) & Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire (PISQ-12). An independent clinician performed the 12-month follow-up. Primary outcome was the patient-reported success rate for SUI on Patient Global Impression of Improvement Questionnaire- PGI-I; defined as "Very Much Improved/Much Improved". Secondary outcomes included impact on women's QOL and peri-operative complications. Multivariate regression model was used to assess potential risk factors for failure of TO-TVT with concomitant POP repair including the TO-TVT surgical approach used outside-in versus inside-out.

Results:
121 women (91%) completed 12 month follow-up; patient-reported success rates for TO-TVT with and without concomitant POP repair were 61% and 79.5% at 12 month respectively; $p<0.001$ OR 2.995 95%CI 1.690, 5.307 (Table 1). 28 women declined to attend for pad test; 77% ($n=72/93$) had negative ICS 1-h pad test at 12 month which was significantly lower than 91% ($n=210/230$) in the control group ($p=0.0013$, OR 0.112 95%CI 1.57, 5.975). Analysis of KHQ showed median (IQR) postoperative KHQ improvement of 27.5 (−1.7, 43.2) points versus 35.1 (16.4, 53.1) in the study and control groups (Table 1) respectively ($p=0.001$). Multivariate regression analysis showed BMI>30 kg/m^2 ($p=0.017$, OR0.932 95%CI 0.879, 0.987) and previous continence surgery ($p=0.001$, OR0.324 95%CI 0.164, 0.638) to be independent risk factors of failure of TO-TVT with concomitant POP repair (Table 2). Results of prolapse surgery in the study group were comparable to the current literature (Table 3).

Conclusion:
Transobturator tension free vaginal tapes are associated with significantly lower patient-reported success rates in management of symptomatic female stress urinary incontinence when associated with concomitant POP repair.

References:
1.http://www.lindalliance.org/Whats_new.asp (Accessed on 15th December 2010)

Table 1: Patient-reported Outcomes

Characteristics	Group Control Group ($n=299$)	Study GROUP ($n=121$)	p	95% CI (if applicable)
PGI-I, n (%)			**<0.001**	
Failure	60 (20.5)	47 (38.8)		
Success	232 (79.5)	74(61.2)		
Median improvement in KHQ Domains (quartiles)				
General Health	0 (0,0)	0 (−25,0)	**<0.001**	
Incontinence Impact	66.7 (33.3, 100)	33.3 (0, 66.7)	**0.001**	
Role Limitation	50 (16.7, 83.3)	33.3, (0, 66.7)	**0.012**	
Physical Limitation	50 (16.7, 66.7)	33.3, (0, 66.7)	**0.005**	

Social Limitation	22.2 (11.1, 55.6)	11.1 (11.1, 55.6)	**0.021**	
Personal Relation	1 (0, 33.3)	16.7 (0,66.7)	0.199	
Emotions	33.3 (11.1, 66.7)	22.2 (−11.1, 50.0)	**<0.001**	
Sleep/Energy	16.7 (0, 50)	16.7 (−16.7, 33.3)	**0.002**	
Severity Measures	50 (16.7, 66.7)	33.3 (−8.3, 58.3)	**<0.001**	
Average KHQ	35.1 (16.4, 53.1)	27.5 (−1.7, 43.2)	**0.001**	
Mean improvement in PISQ12 score (SD)	4.9 (7.1)	6.5 (6.0)	**0.082**	−1.6 (−3.4, 0.2)

Table 2: Logistic Regression For Primary Outcome - PGI-I;*

	Odds Ratio (95% CI)	p value
TO-TVT with prolapse repair	2.995 (1.690, 5.307)	**<0.001**
Age	1.003 (0.979, 1.028)	0.817
BMI	1.073 (1.013, 1.137)	**0.017**
Parity	0.937 (0.754, 1.165)	0.558
Pre-MUCP >30	1.532 (0.794, 2.959)	0.204
Mixed Urinary Incontinence	1.132 (0.625, 2.049)	0.683
Type of TO-TVT Performed	1.382 (0.809, 2.361)	0.236
Previous Continence surgery	3.091 (1.567, 6.097)	**0.001**

*Hosmer and Lemeshow's goodness of fit test χ^2 (8)=7.043, p=0.532

Table 3: Pre & Postoperative (6 Month) Staging Of Prolapse

Number of patients	n=112
Preoperative Stage/Grade Of Prolapse	
B/W grade 4/POP-Q IV	27 (24%)
B/W grade 3/POP-Q III	52 (46%)
B/W grade 2/POP-Q II	34 (30%)
Postoperative Stage/Grade in Same Compartment	
B/W grade 4/POP-Q IV	1 (1%)
B/W grade 3/POP-Q III	1 (1%)
B/W grade 2/POP-Q II	14 (12%)
B/W grade 1/POP-Q I or less	96 (86%)

E-TOT-PR/IUGA abstract V2

Presentation Number: 090

MEDIUM-TERM CLINICAL OUTCOMES FOLLOWING SURGICAL REPAIR FOR VAGINAL PROLAPSE WITH A TENSION-FREE MESH AND VAGINAL SUPPORT DEVICE

T. SAYER[1], J. LIM[2], P. HINOUL[3], J. M. GAULD[4], D. VAN DRIE[5], M. SLACK[6], Prosima Study Investigators;
[1]North Hampshire Hosp., Basingstoke, United Kingdom, [2]Royal Women's Hosp., Melbourne, Australia, [3]Ethicon, Somerville, NJ, [4]Ethicon, Livingston, United Kingdom, [5]Women's Hlth.Ctr. of West Michigan, Grand Rapids, MI, [6]Addenbrookes Hosp., Cambridge, United Kingdom.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:
This follow-up study was designed to evaluate clinical outcomes in the medium term following surgery with this polypropylene mesh and vaginal support device (VSD) (GYNECARE PROSIMA™ Pelvic Floor Repair System, Ethicon, NJ) in women with symptomatic vaginal prolapse of Pelvic Organ Prolapse Quantification (POP-Q) Stage II or III.

Background:
Surgery for vaginal prolapse involving a non-anchored, tension-free placement of pre-cut polypropylene mesh and use of a VSD placed in the vaginal lumen has previously been described[1]. The VSD acts as an intra-vaginal splint to stabilize the vagina and mesh implants during the early post-operative period, when excessive movement of healing vaginal tissues may challenge tissue in-growth resulting in compromised surgical outcome. Previously reported 1 year clinical outcomes indicated that this repair was associated with improved anatomical and functional outcomes, with a low rate of complications[2]. Here we report ≥2 years results to assess durability of the repair.

Methods:
This study was an extension to a prospective, multi-centre, single-arm study. Subjects were to be assessed ≥2 years post-operatively. Evaluations included POP-Q for anatomy, and the following standardized questionnaires: Patient Global Impression of Change (PGI-C), Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Complications during this period were recorded.
Anatomic success was defined as: 1) POP-Q Stage 0-I; 2) leading edge above the hymen (i.e. all POP-Q values were less than 0 cm). Patients requiring re-intervention for prolapse in the treated compartment were considered failures.

Results:
Of the original 150 patients enrolled, 121 patients re-consented to extended follow-up, including 11 Device Run In patients, included for safety evaluation only. Mean age was 65 years old and median length of follow up was 29 months (range 24–34 months). Those re-consenting were compared to those not returning in terms of demographics, surgical characteristics and 1 year outcomes; there were no significant differences between the groups.
Anatomic success at ≥2 years was 69.1% (95%CI: 59.6–77.6%) using POP-Q Stage 0-I, and 84.5% (95%CI: 76.4-90.8%) when defined as leading edge above the hymen. Leading edge data are reported in Table 1. A difference of 2 cm or less between TVL and point C was observed in 85.3% and 83.6% of patients at 1 year

and ≥2 years, respectively, indicating apical support was maintained in the medium term.

Patient reported outcomes are presented in Table 2. Responses to PGI-C revealed 83% patients felt "much better" at ≥2 years (versus 77% at 1 year). Responses to PFDI-20 and PFIQ-17 questionnaires showed prolapse symptoms and related impact were significantly improved and sustained over time.

In sexually active women, PISQ-12 scores were significantly improved from baseline. Resolution of dyspareunia was reported in 7 of 10 patients reporting pre-existing symptoms. Nine out of 60 women not previously sexually active resumed sexual activity. The incidence of *de novo* dyspareunia was 4 of 41 (9.8%) sexually active women, with 2 women reporting the onset of dyspareunia between 1 year and ≥2 years.

The cumulative mesh exposure rate for this extended follow up period was 9.1%, the majority being reported and resolved within the first year following surgery. In 1 patient, a recurrent episode of mesh exposure was identified at approximately 28 months, and successfully treated with topical oestrogen. One patient had a TVT-O sling placed for worsening stress urinary incontinence. Two patients required re-intervention for recurrent prolapse in the anterior wall: one underwent an anterior mesh repair at 9 months, and the other patient underwent sacrocolpopexy at 25 months.

Conclusions:

These results indicate that this vaginal repair using a non-anchored, tension-free mesh and VSD is a safe and effective treatment for women with symptomatic vaginal prolapse at ≥2 years. Significant improvements were observed in both anatomical and functional outcomes, and complication rates were low.

References (optional):

1. Br J Ob Gyn 2008;15:391–397
2. Am J Obstet Gynecol 2010; 203(6):587.e1–8

Presentation Number: 091

ANALYSIS OF LEARNING CURVE OF BILATERAL ANTERIOR SACROSPINOUS LIGAMENT SUSPENSION WITH MESH

R. DE TAYRAC, S. GAILLET, J. L. FAILLIE, L. BOILEAU, G. TRIOPON, P. COSTA, P. MARES, V. LETOUZEY;
CHU Carémeau, Nîmes, France.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of this study was to analyse the learning curve of bilateral anterior sacrospinous ligament suspension associated with anterior mesh repair in a single centre.

Background:

The bilateral anterior sacrospinous ligament suspension associated with vaginal mesh repair is a challenging surgical technique requiring a significant level of skill and training, which yields a very high success rate, however is not without potential ureteral and neurologic complications.

Methods:

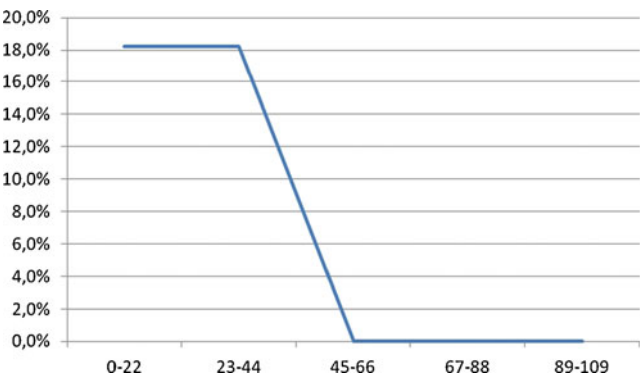
The first 109 bilateral anterior sacrospinous ligament suspension associated with anterior mesh repair performed by three surgeons trained together in a single center were analysed retrospectively for pre-operative, operative and post-operative data. To discover a turning point, all major complications were reported and the study population was divided into 5 equal groups of 22 interventions each, classed chronologically. Statistical analysis was carried out by Cochran-Armitage trend test. Other descriptive statistics were computed with the use of standard methods for means, medians and proportions.

Results:

One-hundred and nine patients were operated between March 2007 and December 2010. All anterior sacrospinous suspension were done using the Capio® (Boston Scientific), while the mesh used was the anterior-apical Pinnacle® (Boston Scientific) in 79 patients, the Polyform® (Boston Scientific) in 23 and the UpHold® (Boston Scientific) in 7. Mean age was 70 years old. Twenty-six patients (24%) had been previously operated for a genital prolapse. All patients had both anterior vaginal wall prolapse and a Level 1 defect; stage 2–4 (POP-Q). The mean follow-up was of 20.5±7.4 months. During this period, 5 patients (4.6%) presented with a recurrence of anterior vaginal wall prolapse and 3 patients (2.8%) presented a vaginal erosion. Regarding satisfaction, 101/109 (92.7%) patients were totally satisfied or satisfied and 8 (7.3%) not satisfied. In the all series, eight major perioperative complications occurred: four ureteral kinking (3.7%; patients 7, 19, 41, 42), three operative site infections (2.8%; patients 4, 38, 44) and one sciatic pain (0.9%; patient 14). The learning curve showed a dramatic decrease in the complication rate with a turning point after 23–44 procedures (p=0.002) (Fig. 1).

Conclusions:

The learning curve of bilateral anterior sacrospinous ligament suspension associated with anterior mesh repair shows a steady decrease in the rate of major complication. A turning point was observed after 23–44 procedures. During the learning curve there is no increased failure rate. Anatomical results at medium term have confirmed promising results at short term.



Presentation Number: 092

SHOULD MESH BE USED FOR CYSTOCELE REPAIR? LONG- TERM OUTCOMES OF A CASE- CONTROL SERIES

V. WONG[1], K. SHEK[1], J. GOH[2], A. RANE[3], H. DIETZ[1];
[1]Univ. of Sydney, Penrith, Australia, [2]Griffith Univ., Brisbane, Australia, [3]James Cook Univ., Townsville, Australia.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To compare long-term subjective and objective outcomes after Anterior Colporrhaphy with and without transobturator mesh placement.

Background:

Mesh reinforcement of anterior colporrhaphy for cystocele repair has become very popular in recent years. Although there is some evidence that mesh may reduce recurrence rates(1), mesh- specific complications such as erosion and chronic pain syndromes are a significant drawback. With this case- control series we aimed to define the effect of mesh use on long-term subjective and objective outcomes, including imaging assessment of prolapse recurrence.

Methods:

We sourced data for a case- control study from a database of 183 patients who underwent anterior vaginal prolapse repair in three tertiary centres between Jan 1998–Oct 2008. 83 patients had undergone anterior colporrhaphy, and this data has previously been published (2). 100 women had had anterior vaginal meshes inserted (49 Prolift™, 51 Perigee™). All patients were seen for post-surgical audit appointments which involved a standardised interview, an ICS POP-Q clinical examination along with a 4D translabial pelvic floor ultrasound using GE Kretz Voluson 730 expert and Voluson I systems(2). Ultrasound data analysis was performed using proprietary software. Avulsion of the puborectalis muscle was diagnosed on tomographic ultrasound. Paired T-test and Chi^2 test statistical analysis was conducted using MiniTab version 13.1. Ethical approval had been obtained at all three sites.

Results:

To enable matching, both groups (mesh and non-mesh) were tested for potential predictors of recurrent anterior vaginal wall prolapse, defined as POPQ ≥ Stage 2. Neither age, BMI, vaginal parity, previous prolapse repair nor anti-incontinence procedures and previous hysterectomy were significant or near-significant predictors. The only significant predictors of recurrence were length of follow-up (for both groups) and avulsion injury (in non-mesh group only). Consequently, in order to match the two groups for these two predictors of recurrence, we removed 49 datasets in a blinded fashion, leaving a total of 67 patients in each group for analysis. Demographic data is given in Table 1.

Table 1: Demographic data.

Parameter	Mesh *N=67*	No mesh *N=67*	P
Age (years)	66.1	60.9	0.005
BMI	28.5	28.6	n.s
Previous vaginal delivery	3.18 (SD 1.5)	3.21 (SD 1.6)	n.s
Previous prolapse surgery	21/67 (31%)	4/67 (6%)	<0.001
Levator avulsion	22/67 (33%)	23/67 (34%)	n.s
Follow-up period in years	3.93 (SD 0.68)	4.12 (SD 0.69)	n.s

All results favoured the mesh group, except for symptoms of recurrent prolapse (see table 2). A recurrent cystocele of ≥ stage 2 was observed in 21/67 (31%) in the mesh group and 37/67 (55%) in the non-mesh group.

Table 2: Outcome measures *on ultrasound, relative to symphysis pubis, in mm. Negative numbers signify greater descent below symphysis pubis.

Outcome measure	Mesh *N= 67*	No mesh *N=67*	P
Overall satisfaction	53/67(79%)	40/67(60%)	0.015
Prolapse symptoms	15/67(22%)	22/67(33%)	n.s.
Point Ba	−1.79	−1.06	0.004
≥ Stage 2 cystocele	21/67 (31%)	37/67 (5%)	0.005
ean maximal bladder descent on Valsalva*	−0.7 (SD 11.0) mm	−8.3 (SD 15.9) mm	.002

Sub-analyses were conducted in patients with levator avulsion and those without. In patients with intact puborectalis muscle, all statistically significant differences between mesh and non-mesh groups disappeared. The opposite was the case for women with levator avulsion (Table 3).

*Table 3: Outcome measures in women with avulsion of the puborectalis muscle. *on ultrasound, relative to symphysis pubis.*

Outcome measure	Mesh *N= 22*	No mesh *N=23*	P
Overall satifaction	16/22 (73%)	12/23 (52%)	n.s
Prolapse symptoms	7/22(32%)	7/23(30%)	n.s
Point Ba	−1.68	−0.17	0.003
≥ Stage 2 cystocele	8/22 (36%)	18/23 (78%)	0.004
Mean maximal bladder descent on Val alva*	−1 (SD 13.9) mm	−17.6 (SD 14.8) mm	<0.001

Conclusions:

At 4 years follow-up, mesh augmentation of anterior colporrhaphy was associated with significantly better objective anatomical outcomes in this case control series. However, this effect was only significant in women diagnosed with avulsion of the puborectalis muscle on 4D translabial ultrasound. Our results suggest that the use of transobturator meshes improves long-term anatomical outcomes. Patients most likely to benefit from mesh use are those in whom the puborectalis muscle is detached from its insertion on the inferior pubic ramus.

References:

1. Cochrane Database of Systematic Reviews Cochrane Database of Systematic Reviews. 2010(4):DOI: 10.1002/14651858.CD004014.pub4.
2. Ultrasound Obstet Gynecol. 2004;23(6):615–25.
3. Ultrasound Obstet Gynecol. 2010;36:76–80.

Presentation Number: 093

EXPERIMENTAL EVALUATION OF THE EFFECT OF AGE, PARITY AND HORMONAL STATUS ON SURGICAL REPAIR OF FASCIAL DEFECTS

S. MANODORO[1], E. WERBROUCK[1], Y. OZOG[1], D. DE RIDDER[1], D. E. RIZK[2], J. DEPREST[1];
[1]Katholieke Univ.it Leuven, Leuven, Belgium, [2]United Arab Emirates Univ., Al Ain, United Arab Emirates.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

We hypothesize that age, parity and hormonal depletion may influence normal wound healing following fascial repair. We used a full thickness abdominal wall rat model and documented the host response and visco-elastic properties.

Background:

Pelvic organ prolapse (POP) is a common problem that will become an even larger challenge as the population is aging. Age and menopausal status are independent risk factors in its development. A probable mechanism for acceleration of POP during menopause is a rapid and progressive deterioration of the biomechanical properties of pelvic supportive tissues. Estrogen and progesterone dependent adverse changes in the collagen I:III ratio have already been identified.

Surgery is the mainstay of therapy and usually involves repair of the fascial defect, using native tissues. As this fails in 30%, implant augmented repair is increasingly being used. These are foreign bodies, which by definition induce an inflammatory response. The specific effects of age, and hormonal status, on surgical repair have not been studied in detail so far.

Methods:

Thirty-four Wistar female rats were divided into 5 groups: Young (3 months) Virgins (YV), Young Parous (YP; 3 months), Old (13 months) Virgins (OV), Old Parous (OP) and Young rats that were Ovariectomized 8 weeks prior to implantation (Y OVX; 4 1/2 months aged at the time of implantation). As external controls 6 Young (3 months) Male rats were added. The rats were operated under general anaesthesia and sterile conditions. Each rat served as its own control by performing two simultaneous abdominal wall procedures on either side. On the right side, a standardized paramedian 3 cm incisional defect was created and closed with continous ProleneTM 4/0 (Ethicon, Dilbeek, Belgium) at 0.5 cm inter run distance (native tissue repair). On the left side a standardized 2×3 cm defect was made and covered by UltraproTM (Johnson & Johnson, Norderstedt, Germany) 2.5×3 cm implant. Euthanasia was performed on day 180 to remove explants, containing both the mesh and native tissue. Biomechanical tests were performed with a 500 N Uniaxial Tensiometer with a 200 N load-cell (Zwick GmbH & Co. KG, Ulm, Germany).

Hematoxylin-eosin (H&E) stained sections were used to quantify the presence of foreign body giant cells (FBGC), polymorphonuclear (PMN), and newly formed vessels at the interface of the implant material. Organization, composition, and amount of collagen were assessed semi-quantitavely analyzing Movat-stained slides. Immunohistochemical staining was done with a primary monoclonal mouse ED1 antibody.

Results:

AGE: mesh explants of young rats displayed more neovascularization than old rats. There were no differences in native tissue repair explants between young and old rats. Biomechanical measurements were not different both in mesh augmented and native tissue repairs .

PARITY: mesh explants of parous rats displayed more neovascularization than virgin rats. Native tissue repair explants of parous rats displayed lower FBGC and macrophages counts than virgin rats. Biomechanical measurements were not different between mesh augmented and native tissue repairs.

HORMONES: in mesh augmented repair explants, reproductive young rats (3 months) had lower PMN counts than male and castrated (menopausal) rats; male rats had lower macrophages counts than castrated rats. In native tissue repair explants reproductive rats had lower macrophages counts than castrated rats; in reproductive rats collagen architecture was less mature than in male and castrated rats; males had a lower amount of collagen than castrated rats. Biomechanical analysis in mesh augmented repair explants displayed no difference in the stress required for disruption, but reproductive rats had lower strain than castrated rats. In native tissue repair explants, reproductive rats had lower max stress than male and castrated rats, but there were no differences in term of strain.

Conclusions:

In this rat model, age, parity and female sex hormones do not have measurable effects on the inflammatory response and collagen characteristics to mesh augmented and native tissue repair. On tensiometry, female sex hormones increase resistance to deformation in mesh augmented repair but reduce tensile strength in native tissue repair.

References:

J Surg Res 2002;103:190–202
Int Urogynecol J Pelvic Floor Dysfunct 2006;18:619–626

Presentation Number: 094

ANATOMY OF PELVIC ARTERIES ADJACENT TO THE SACROSPINOUS LIGAMENT IN PELVIC ORGAN PROLAPSE: IMPORTANCE OF TVM PROCEDURE FOR POP PATIENTS

S. HONGOH, H. MIYAKITA, T. TERACHI, T. IWATA;
Tokai Univ., Oiso, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

It becomes tension free vaginal mesh (TVM) procedure alternative to pelvic organ prolapse(POP) surgery. But a part of this surgery needs blind approach for mesh fixation. The objective of this study is to determine the arterial vascular anatomy for POP patients, on the area of the sacrospinous ligament specially.

Patients and methods:
We studied the pelvic arterial vascular anatomy using 6 to 64ch multi-slice CT angiography with 17 cases of POP patients (mean age 67.7 y/o) and 15 female normal controls (mean age 75.6 y/o). The slice was 1.25 mm interval. We made the reconstruction of 3D and maximum intensity profile for the pelvic artery. We focused where running and size of the inferior gluteal artery and internal pudendal artery, and measure the length from coccygeal branch of inferior gluteal artery to ischial spine.
Results:
CT angiography could detect the fine artery 1 mm in size. There were 3 arteries which were inferior gluteal artery, internal pudendal artery and coccygeal branch of inferior gluteal artery lied around the sacrospinous ligament. There was 3 mm mean window in which the inferior gluteal artery was left mid-portion between ischial spine and sacrum in front of the exact sacrospinous ligament in POP patients. Moreover, the coccygeal branch of inferior gluteal artery lied 5.7 mm above lower edge of the coccygeal muscle, and this artery was branched off 2 lines which lied 5 mm and 10 mm above the edge of the coccygeal muscle.
Conclusions:
In TVM procedure, the inferior gluteal artery injury can be avoided normal manipulation but coccygeal branch of inferior gluteal artery could be injured in this procedure because thick arteries lied in the area of pass for TVM leg.

Presentation Number: 095
THE EFFECT OF PROLAPSE SURGERY ON VAGINAL SENSIBILITY AND VAGINAL BLOOD FLOW
M. M. LAKEMAN[1], E. LAAN[1], S. BOTH[2], J. P. ROOVERS[1];
[1]Academic Med. Ctr. Amsterdam, Amsterdam, Netherlands, [2]Leiden Univ. Med. Ctr., Leiden, Netherlands.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To assess the effects of prolapse surgery on vaginal sensibility, vaginal blood flow and sexual function.
Background:
Prolapse surgery has been shown to have major impact on sexual function. Since prolapse surgery not only influences psychological factors but also physiological conditions, there is a need for objective outcome measurements. Genital response can be assessed by vaginal pulse amplitude (VPA) using photoplethysmography and we recently validated a new method to measure vaginal sensibility. We incorporated this method of measuring vaginal wall sensibility in a vaginal combi-probe also containing VPA measurement. This enabled us to objectively assess the effects of prolapse surgery on vaginal blood flow and vaginal wall sensibility.
Methods:
Patients scheduled for prolapse surgery were asked to participate in an observational study using this new combi-probe before and six months after surgery. Measurements were performed during non-erotic and erotic conditions using visual sexual stimulation. Sexual functioning was assessed using validated questionnaires (FSFI, FSDS-R).
Results:
Up till now 18 patients underwent pre- and post-operative measurement. The performed procedure depended on the type of prolapse, in case of uterine descent a sacro-spinous ligament fixation ($n=5$) or manchester ($n=1$), for a cystocele an anterior colporhaphy ($n=13$), in case of a rectocele posterior colporhaphy ($n=8$) and in case of stress urinary incontinence a TVT ($n=1$) was performed.
The sensibility of the cranial anterior ($p=0.02$) and caudal anterior ($p=0.09$) vaginal wall decreased after prolapse surgery. VPA analysis showed a reduction in vaginal blood flow during erotic ($p=0.02$) and non-erotic ($p=0.10$) conditions. However the response to sexual stimuli did not change ($p=0.49$).
Comparing women with and without anterior and/or posterior colporhapphy did not show any difference in vaginal sensibility and vaginal blood flow. In women after sacro-spinous ligament fixation vaginal wall sensibility was more decreased in the cranial posterior vaginal wall ($p=0.02$) and vaginal blood flow during baseline was significantly decreased ($p=0.02$) however a greater response to sexual stimuli was found ($p=0.01$).
Sexual functioning improved after surgery (mean FSFI total pre-operative 21.1 (SD 12.6), post-operative 25.4 (SD 5.4) $p=0.08$) and sexual distress decreased (mean FSDS-R pre-operative 21.1 (SD 12.6), post-operative 14.0 (SD 10.3) $p=0.07$), even though post-operative means for both questionnaires were still within the sexually dysfunctional range. When comparing the difference in FSFI domain scores between women with and without sacro-spinous ligament fixation a smaller increase in the lubrication domain was found in women with sacro-spinous ligament fixation ($p=0.09$).
Conclusions:
We are the first to show a decrease in vaginal blood flow and vaginal sensibility due to prolapse surgery, mainly due to sacro-spinous ligament fixation. Decreased vaginal blood flow and sensibility may be related to post-operative sexual dysfunction. Even though the validated questionnaires showed an improvement, mean values were still within the dysfunctional range. We speculate that the reported improvement is related to improved body image and reduced fear of urinary incontinence during sexual activity. Future studies are needed to tease out more precisely the contribution of psychological and physiological factors on sexual function.
References:

Presentation Number: 096
INCONTINENCE DURING INTERCOURSE: MYTHS UNRAVELLED
S. JHA, K. STRELLEY, A. DUA, S. RADLEY;
Jessop Wing, Royal Hallamshire Hosp., Sheffield, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
This study aimed to establish the prevalence of urinary leakage during intercourse, the extent to which urinary leakage impacts on sex life and the correlation between different urodynamic diagnosis and coital leakage.

Background:
The association between different types of urinary incontinence and coital incontinence is poorly understood. It is believed that a urodynamic diagnosis of detrusor overactivity is associated with orgasm incontinence and urodynamic stress incontinence is associated with penetration incontinence.

Methods:
480 women attending the Urogynaecology Unit between January 2006 & December 2010 referred with urinary incontinence and subsequently undergoing urodynamics formed the study group. Patients with prolapse, voiding dysfunction, hypersensitivity on urodynamic studies, previous prolapse or incontinence surgery were excluded from the analysis. Data were collected as part of routine clinical care using a validated questionnaire and correlated with urodynamic findings.

SPSS version 17 was used for data analysis. Pearson's Rank Correlation was used to establish the association between severity of urinary incontinence and its impact on sex life. Kruskal-Wallis test was used to compare the different parameters of sexual function with different urodynamic diagnoses ie Urodynamic stress incontinence (USI), detrusor overactivity (DOA), mixed incontinence (USI + DOA) and normal urodynamics. Chi square test was used to compare orgasm and penetration incontinence in different urodynamic diagnosis.

Results:
350 out of the 480 women were sexually active. The overall frequency of different urodynamic diagnosis is shown in table 1. 211/350 (60%) of women undergoing urodynamics and 12/31 (38%) of women with normal urodynamics had leakage during intercourse. Pearsons rank correlation demonstrated that overall quality of life in women with urinary incontinence was strongly correlated to the impact of urinary symptoms on sex life ($r=0.659$, $p<0.01$). The parameters of sexual function were no different with different urodynamic diagnosis. Table 2 shows the results of the Kruskal-Wallis test comparing different parameters of sexual function in the different UDS diagnosis (USI, DOA and mixed). In women with normal urodynamics, incontinence with intercourse was less likely ($p=0.035$).

The prevalence of orgasm incontinence alone with no penetration incontinence ($n=56$) was not significantly different in women with USI (34/201;16%), DOA (11/67; 16%), mixed incontinence (7/51; 14%) and normal urodynamics (4/31,13%). Likewise there was no significant difference in the prevalence of penetration incontinence with no orgasm incontinence ($n=51$) in women with underlying USI (30/201; 15%), DOA (11/67; 16%) and Mixed incontinence (9/51; 18%). In women with normal urodynamics penetration incontinence alone was unlikely (1/31; 3%; $P<0.005$).

Conclusion:
Incontinence during intercourse is a common problem in women with urinary incontinence and is reported in 60%. The different parameters of sexual function i.e., overall impact on sexual function, incontinence with intercourse, penetration incontinence, orgasm incontinence, patient avoidance, partner avoidance, anxiety and postcoital infections are not influenced by the underlying urodynamic diagnosis. The presence of specific symptoms i.e. orgasm or penetration incontinence in isolation is not prognostic of underlying urodynamic diagnosis. Worsening urinary incontinence significantly impacts on and causes deterioration in sex life.

References:
[1] Hilton P. Urinary incontinence during sexual intercourse: a common, but rarely volunteered, symptom. *Br J Obstet Gynaecol* 1988; 95(4):377–381.

Table 1 Incidence of UDS Dx in study population (Total 350)

Urodynamic Diagnosis	N (%)
Urodynamic stress incontinence	201 (58)
Detrusor overactivity	67 (19)
Mixed incontinence	51 (14)
Normal	31 (9)

Table 2: Comparison of different parameters of sexual function with different Urodynamic Diagnosis. (Kruskal-Wallis test)

	USI/DOA/Mixed (Significance)
Overall impact	.575
Incontinence with sex	.698
Orgasm incontinence	.718
Penetration incontinence	.406
Patient avoids intercourse	.084
Partner avoids intercourse	.125
Anxiety	.871
Postcoital infections	.802

Table 3 Underlying urodynamic diagnosis in women with specific symptoms

Urodynamic Dx	Penetration 147 (%)	Orgasm 153 (%)	No leakage 139 (%)	Leakage with intercourse 211 (%)
USI	85 (58%)	89 (58%)	73 (53%)	128 (61%)
DOA	28 (19%)	28 (18%)	31 (22%)	36 (17%)
Mixed	27 (18%)	25 (16%)	16 (11%)	35 (16%)
Normal	7 (5%)	11 (8%)	19 (14%)	12 (6%)

Presentation Number: 097

MESH IMPACT ON SEXUAL FUNCTION

R. EL HADDAD, A. MARTAN, K. ŠVABÍK, J. MAŠATA, T. KOLEŠKA, P. DRAHORÁDOVÁ, P. HUBKA;
First Med. Faculty and Gen. Univ. Hosp., Charles Univ., Prague, Czech Republic.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The current evidence of pelvic floor surgery on sexual function is conflicting [1]. Our aim was to assess the impact of transvaginal anterior repair using two mesh implantation techniques on sexual function.
Background:
Pelvic organ prolapse is a major health problem affecting 50% of parous women over 50 years of age. The common site of prolapse is the anterior vaginal wall. The anterolateral vaginal walls are densely innervated by pelvic autonomic nerves which are critical for preserving sexual function. Surgery in this region for cystocele repair may affect this innervation and alter sexual experience [2]. Furthermore, there is very litle information about the influence of Meshes that are increasingly used to reinforce vaginal repairs on sexual function.
Methods:
Women with symptomatic stage II or greater prolapse of the anterior compartment referred to a tertiary urogynaecological unit between September 2007 and may 2009 were recruited to join the prospective study. They were assessed with a standardised interview that included questions about symptoms of urinary incontinence, pelvic organ prolapse POP and sexual function. All patients had urodynamic examination, pelvic floor ultrasound, pelvic assessment according to the International Continence Society POP- Quantification. Patients were divided according to a protocol into two respectively three groups: the mesh group, treated with anterior colporrhaphy augmented by individualised mesh without lateral fixation (Mesh; n=33); the Prolift group, treated with a Prolift anterior® fixated through obturator foramen and arcus tendineus fascia pelvis using four trocar-guided extension arms (Prolift; n=36); the third group contained patients who refused mesh operations and underwent the traditional anterior repair (AR group; n=18). Sexual function was assessed by inviting the patients to complete the validated and self administrated short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire PISQ-12 before and 4–6 months after surgery—after resuming their sexual activity. All data were processed and statistical analyses performed in statistical environment R, version 2.9.1. Continuous data were summarized as a mean with standard deviation and as median or quartile range (QR); Categorical data were summarized in absolute and relative frequencies. Wilcoxon and Kruskall-Wallis test were used when the assumption of normality was not met. All tests were performed at 5% level of significance.
Results:
87 women participated in this study. Demographic data showed no statistically significant difference between any of the groups. The mean age was 60.4 (SD 9.8), mean parity 2.0 (SD 0.5) and mean BMI 27.5 (SD 3.9). Before surgery 50 women were sexually active and 35 were not. From this group 2 women renewed their sexual activity after surgery, decreasing the number of sexually inactive women to 33. There was no stop in sexual activity after surgery. We did not had the data of 2 women (2.2%) before and 6 women (6.8%) after surgery, leaving 45 sexual active patient completing PISQ-12 questionnaires before and after surgery. When comparing their PISQ scores, there is a 4.5 point statistically significant increase (table 1). PISQ score increased after surgery in all groups (table 2). We did not have any case of severe dyspareunia needing surgical intervention. In AR group 30% patients answered positive the question: Do you feel sometimes pain during sexual activity? In the prolift group there was 10% patients with positive answer and 6% in the mesh group.

Table 1. PISQ score before and after surgery

	N	Before surgery median (QR)	After surgery median (QR)	Difference median	Wilcoxon test P value
PISQ score	45	31.0 (5.0)	36.0 (7.0)	4.5	**0.0001**

Table 2. Impact of different techniques of anterior repair on sexual function

PISQ score	AR		Prolift		Mesh		Kruskall-Wallis test P value
	N	median (QR)	N	median (QR)	N	median (QR)	
Before surgery	13	32.0 (4.0)	19	33.0 (4.0)	18	29.5 (3.8)	0.1412
After surgery	10	36.0 (5.5)	21	36.0 (5.0)	17	36.0 (6.0)	0.7422
Variation of PISC score as a surgery impact	10	4.5 (7.5)	19	2.0 (5.0)	16	5.5(6.8)	0.3665

Conclusions:
41% of women with POP were not sexually active and the majority of those women remain sexually inactive after surgery.
All sexually active women resume their sexual activity after surgery. Sexual function evaluation was not negatively affected by occasional pain on intercourse.
There was no deterioration of sexual function regardless of the type of surgery. This shows that the mesh insertion with or without lateral fixation by itself does not negatively affect the sexual function, this might be mostly caused by complications.
References:
1) Int Urogynecol J (2009) 20 (suppl 1):S27–S31
2) J Urol (2006)175:439–446

Presentation Number: 098
LEVATOR HIATAL AREA AND SEXUAL FUNCTION: DOES SIZE MATTER?
H. L. TERWILLIGER, A. PARSONS, R. BASSALY, L. HOYTE, K. DOWNES, S. HART;
Univ. of South Florida, Tampa, FL.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Determine if a relationship exists between female levator hiatal area and sexual function.

Background:
Most studies in the medical literature have been unable to demonstrate any significant correlation between clinically measured vaginal dimensions and sexual function [1]. However, a relationship exists between levator hiatal dimensions and pelvic organ prolapse [2]. Worsening pelvic organ prolapse is demonstrated to correlate with increasing levator hiatal area, and subsequently greater interference of sexual functioning [2,3]. Also, an increasing number of cosmetic vaginal procedures have been marketed as a way to enhance sexual function in women by altering an enlarged genital hiatus due to childbirth, prolapse or other causes. These procedures are routinely performed to reduce genital hiatal dimensions, although normal introital caliber has not been defined, and consistent scientific evidence demonstrating improved post-operative sexual function is lacking.
The levator hiatal area is a direct measurement of the opening of the pubococcygeus portion of the levator ani muscle, as opposed to a clinical measurement. The question is then raised as to whether the levator hiatal area, given the strong correlation to changes noted during worsening pelvic organ prolapse, can also provide a correlation to sexual function. Since the levator hiatal area is a dynamic measurement depending on the degree of muscle contraction, these potential correlations should be evaluated during rest, maximal kegel and maximal valsalva maneuvers. Translabial four dimensional (4D) ultrasound provides a cost effective and reliable method for measuring the levator hiatal area in an office based setting. The goal of this study is to assess whether there is a correlation between sexual function and levator hiatal area utilizing the validated Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) and translabial 4D ultrasound.
Methods:
The Institutional Review Board approved this study. A retrospective chart review was performed of all adult patients presenting to a urogynecolgy practice from August 2009 through August 2010. During this time period, patients with pelvic floor dysfunction were routinely referred for translabial 4D ultrasound. All patients were administered a series of validated questionnaires, including the PISQ-12, as part of their initial evaluation. Patients who completed the PISQ-12 with no more than 2 unanswered questions, had a complete POP-Q examination, and were referred for translabial 4D ultrasound were included. A GE Voluson E-8 (Waukesha, WI, USA) ultrasound machine was used to acquire the data, with volume reconstruction and analysis of archived cases performed offline using ViewPoint 4DView software. The levator hiatal area was measured by highlighting its boundary in the reconstructed axial image of the plane of minimal hiatal dimension. This was done at rest, maximal valsalva and maximal Kegel contraction. The variables were analyzed using SPSS (version 19.0, IBM Inc., Somers, NY). Correlations were reported using Pearson's and Spearman's correlation coefficients and group comparisons were performed with two-group t-tests. Statistical significance was set at $p<.05$.
Results:
During the study period, 79 patients met the inclusion criteria. The mean age of subjects was 53 with a range of 28–78. The vast majority of the patients reported symptoms of either pelvic organ prolapse or incontinence at their initial visit ($n=78$). One patient presented with post-operative voiding obstruction after a mid-urethral sling placement. One of the subjects had a Stage 0 POP-Q examination, 21 had stage I, 34 had stage II, 17 had stage III and 6 had stage IV. Levator hiatal area ranged from 7.5cm^2 to 37cm^2 at rest, from 11.77cm^2 to 55cm^2 with maximal valsalva and from 6.84cm^2 to 30cm^2 at maximal Kegel. PISQ-12 scores averaged 29 with a range of 8–46 out of a possible 48 points. Positive correlations were found between PISQ-12 scores and levator hiatal area at rest ($r=0.249$, $p=0.027$) and between PISQ-12 scores and levator hiatal area with maximal Kegel ($r=0.276$, $p=0.014$). No correlation was found between PISQ-12 scores and levator hiatal area with valsalva ($r=0.053$, $p=0.640$). There was also no correlation between PISQ-12 scores and total vaginal length or genital hiatus POP-Q measurements.
Conclusion:
Larger levator hiatal areas at rest and with maximal Kegel correlate with better sexual function in an urogynecology practice population.
References:
1. International Urogynecology Journal. 21(4):447–52, 2010 Apr.
2. BJOG 2007;114:882–888.
3. Obstet Gynecol 2002;99:281–9.

Presentation Number: 099
EVALUATION OF THE CLINICAL UTILITY OF THE PFDI-20 AMONG WOMEN IN THE GENERAL POPULATION
A. GAFNI-KANE, R. P. GOLDBERG, P. K. SAND, S. M. BOTROS;
NorthShore Univ. Hlth.System, Univ. of Chicago Pritzker Sch. of Med., Evanston, IL, IL.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

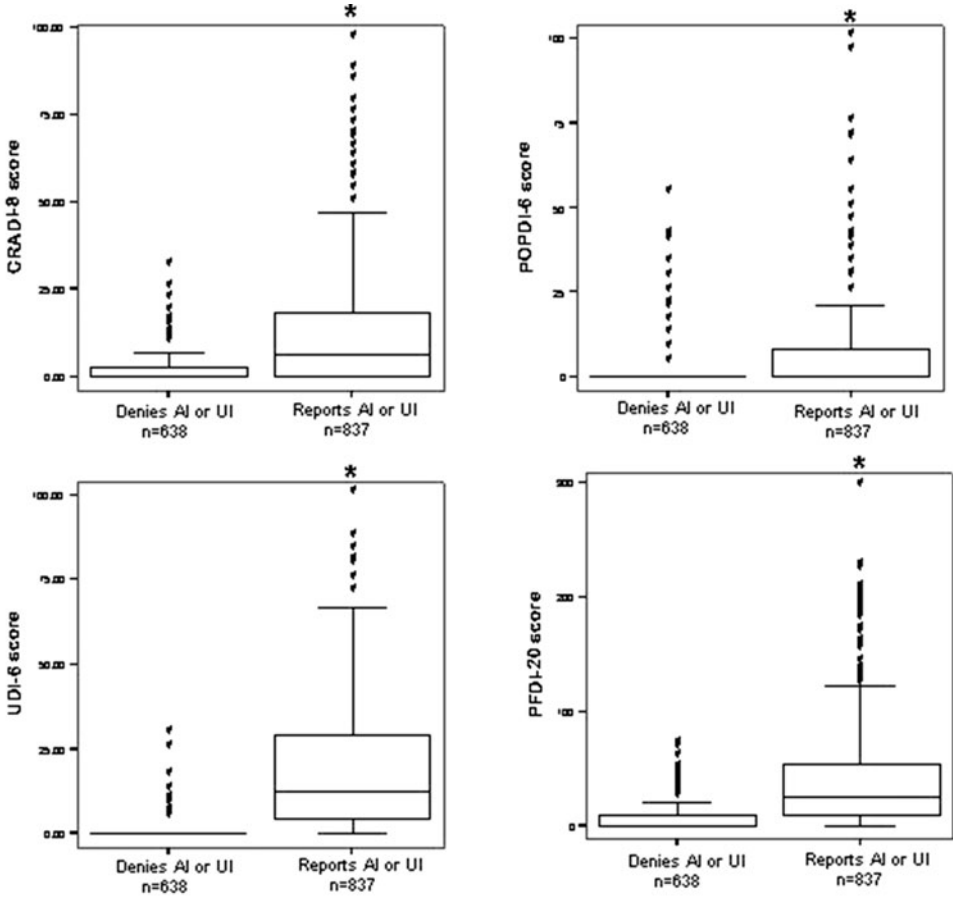
Objective:
Enhance usefulness of the PFDI-20 by establishing score distributions for women in the general population and determine whether scores correspond with symptoms.
Background:
The PFDI-20 was validated among women seen by urogynecologists for pelvic floor dysfunction (PFD).[1] The survey yields valuable information on how quality of life is affected; however a single score is difficult to interpret as reference scores have not been established among women without PFD.
Methods:
Subjects for this cross-sectional study were recruited during Twins Day Festivals from 2004–2009. An anonymous survey on PFD including questions assessing for stress and urgency urinary incontinence (SUI and UUI), as well as anal incontinence (AI) was completed. In 2004, the PFDI was included; the PFDI-20 was used in subsequent years. For 2004 data, PFDI items constituting the PFDI-20 were analyzed. The PFDI-20 was scored as

previously described.[1] Scores were compared between continent and incontinent women and between incontinent subtypes by Wilcoxon rank-sum tests.

Results:

1624 women completed the survey. PFDI-20 and all subscale scores differed significantly between subjects with and without incontinence (Fig. 1), between subjects with SUI only, UUI only, or mixed UI and those denying UI (Fig. 2), and between subjects with AI flatus only, AI liquid stool, or AI solid stool and those denying AI (Fig. 3). PFDI-20 scores differed significantly between subjects with UUI only and SUI only ($p=0.04$). PFDI-20, POPDI-6, and UDI-6 scores differed significantly between subjects with mixed UI and those with SUI only ($p<0.0001$ each). PFDI-20 and subscale scores did not differ significantly between subjects with UUI only and mixed UI or between subjects with AI liquid stool and AI solid stool.

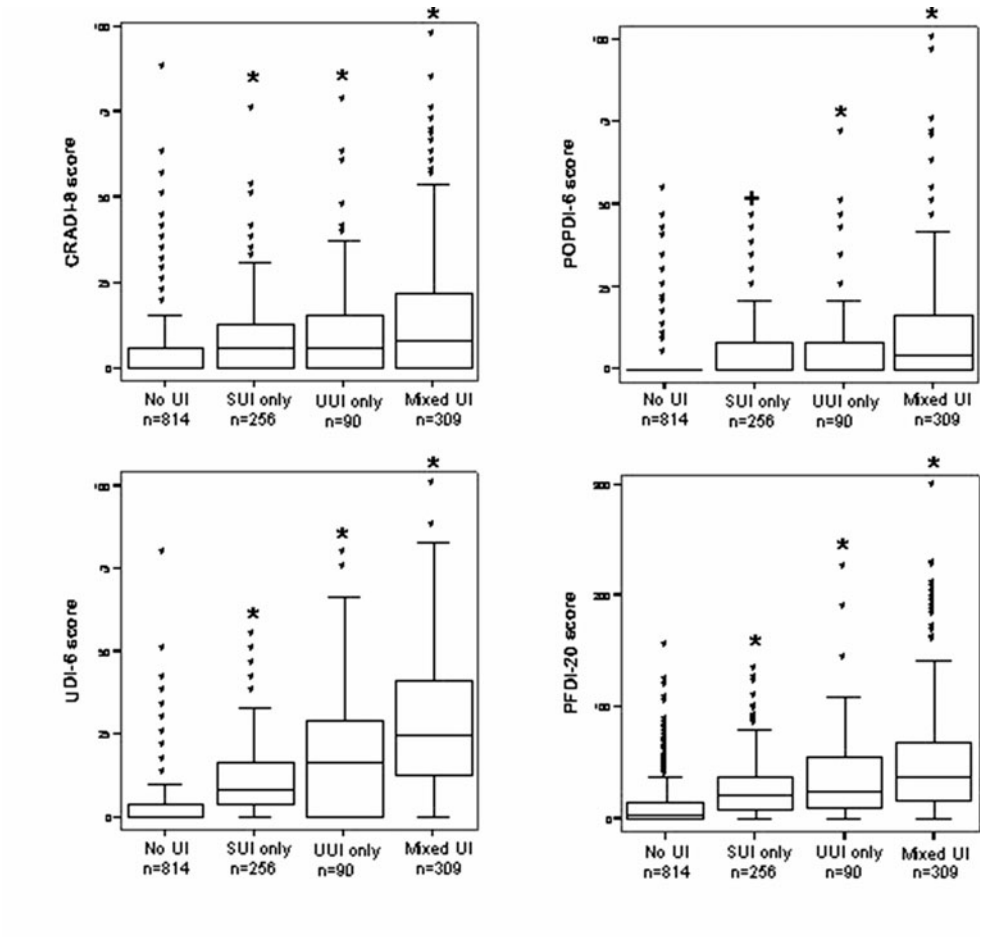
Figure 1. PFDI-20 and subscale scores for women with and without pelvic floor dysfunction



CRADI-8, Colorectal-anal Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory; PFDI-20, short-form of the Pelvic Floor Distress Inventory

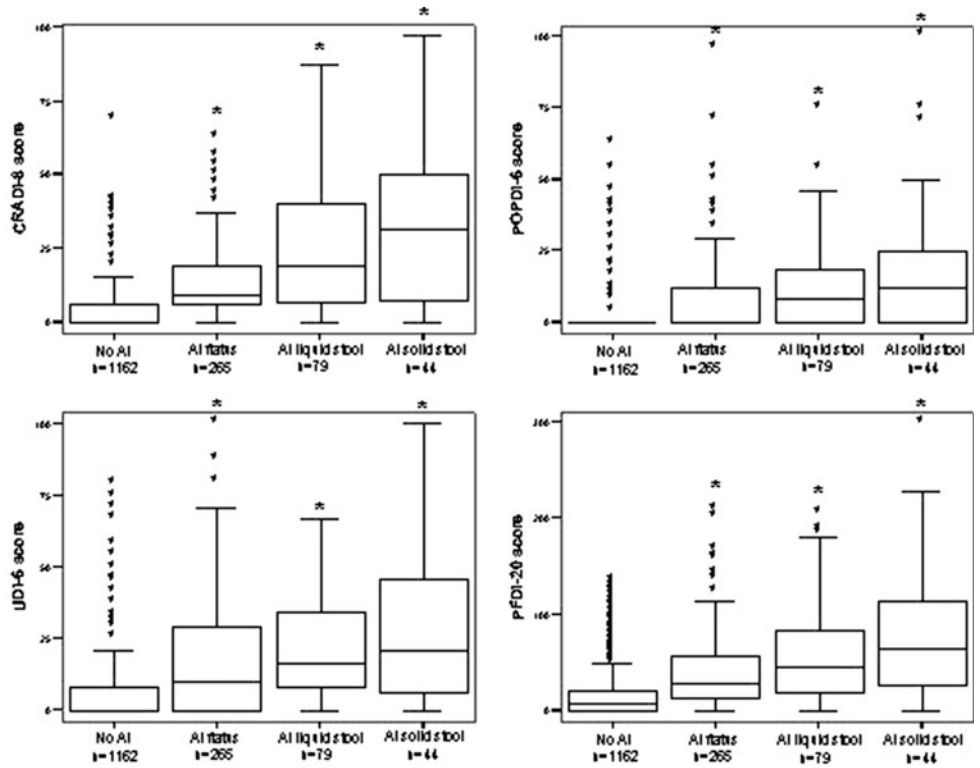
* $p < 0.0001$ when comparing incontinence subtype to no AI or UI by Wilcoxon rank-sum test

Figure 2. PFDI-20 and subscale scores for women with and without urinary incontinence



CRADI-8, Colorectal-anal Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory; PFDI-20, short-form of the Pelvic Floor Distress Inventory
* $p < 0.0001$ when comparing incontinence subtype to no UI by Wilcoxon rank-sum test
• $p = 0.0003$ when comparing incontinence subtype to no UI by Wilcoxon rank-sum test

Figure 3. PFDI-20 and subscale scores for women with and without anal incontinence



CRADI-8, Colorectal-anal Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory; PFDI-20, short-form of the Pelvic Floor Distress Inventory
* $p < 0.0001$ when comparing incontinence subtype to no UI by Wilcoxon rank-sum test

Conclusions:

As improvement in quality of life is a goal for women suffering PFD, it is important to have reference points for interpretation of questionnaire scores. PFDI-20 scores from a sample of the general population correspond with the presence or absence of PFD. These normative and symptom-specific score distributions for the PFDI-20 provide reference points to gauge the effect of disease and intervention on quality of life for women with PFD.

References:

1. Am J Obstet Gynecol 2005;193:103–113

Presentation Number: 100

PHYSICIAN GENDER AND ESTIMATION OF PELVIC ORGAN PROLAPSE QUALITY OF LIFE IMPAIRMENT

M. R. VELLA, R. CARTWRIGHT, D. ROBINSON, L. CARDOZO, I. GIARENUS, W. KAMRAN;
King's Coll. Hosp., London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To measure physician gender disparity in perception of condition specific quality of life impairment for women with pelvic organ prolapse.

Background:

Physician gender, and physician-patient gender discordance [1] each have important effects on clinical consultations, with pervasive implications for the quality of care for many urogenital conditions. Female physicians consistently demonstrate higher empathy ratings [2], a factor that may be associated with improved clinical outcomes.

Evaluation of condition specific quality of life impairment is an essential component of the initial clinical assessment for women with pelvic organ prolapse. Previous work demonstrates that physicians tend to underestimate the impact of prolapse symptoms on quality of life [3].

Methods:

Women planned to undergo surgical correction for symptomatic pelvic organ prolapse were recruited. Patients self-completed the Prolapse Quality of Life Questionnaire (PQoL). This is a 20 item condition specific measure of the severity of the prolapse symptoms and their impact on quality of life, with extensive evidence of validity. At the preoperative assessment a female and a male physician each took a detailed urogynaecological and general medical history, but remained blinded to patients'assessments of their own quality of life. Each physician then completed a further PQoL questionnaire based on their own impressions of the symptoms elicited during the interview. Intraclass correlation (ICC (3,1)) was used to measure reliability of assessments. Multivariate linear regression was used to assess predictors of quality of life mis-estimation. Analyses were conducted using SPSS v19.0.

Results:

Thirty one women were recruited over a period of 9 months. The mean age was 59. 38.7% presented with recurrent prolapse. Intraclass correlations between physician and patient ratings of quality of life (for both male and female physicians) were statistically significant for all 9 domains, and varied between 0.31 and 0.76 (Table 1). Male and female physicians both tended to underestimate quality of life impairment (male mean underestimation 111.2 points, $p<0.0001$; female mean underestimation 117.9 points, $P<0.0001$). There was no observed gender difference in accuracy of ratings ($p=0.69$). Intraclass correlation comparing physician ratings were consistently higher for all domains, varying between 0.43-0.90. The magnitude of impairment ($p<0.0001$) was a strong predictor of mis-estimation for both genders, whereas patient age was not ($p=0.62$).

Table 1: Domain by domain intraclass correlation of patient and physician ratings of quality of life impairment.

	Female Physician Rater		Male Physician Rater	
	ICC	***p***	**ICC**	***p***
General Health Perception (GHP)	0.314	0.04	0.570	<0.0001
Prolapse Impact (PI)	0.518	0.001	0.354	0.023
Role Limitations (RL)	0.501	0.002	0.534	0.001
Physical Limitations (PL)	0.533	0.001	0.533	0.001
Social Limitations (SL)	0.573	<0.0001	0.473	0.003
Personal Relations (PR)	0.766	<0.0001	0.666	<0.0001
Emotions (EM)	0.722	<0.0001	0.764	<0.0001
Sleep/Energy (SE)	0.658	<0.0001	0.615	<0.0001
Severity Measures (SM)	0.523	0.001	0.606	<0.0001

Conclusion:

Both male and female physicians underestimate the impact of prolapse symptoms upon quality of life of their patients. This further highlights the necessity of patient completed questionnaires as part of a full clinical evaluation. While female physicians may be more empathetic, this study fails to show any gender difference in perception of patients' prolapse symptoms. This suggests that male physicians may be able to compensate for any negative impacts of gender discordance upon clinical consultation.

References:

1. 2. J Sex Med. 2010;7(7):2499–508
2. Am J Psychiatry. 2002;159(9):1563–9.
3. Int Urogynecol J Pelvic Floor Dysfunct. 2008;19(4):517–20

Presentation Number: 101

GOAL ASSESSMENT IN WOMEN WITH URINARY SYMPTOMS: WHAT DOES IT SHOW?

G. VIJAYA, S. HEWETT, C. HENDRICKEN, G. DIGESU, A. DERPAPAS, C. REDDINGTON, R. FERNANDO, V. KHULLAR;
ST.MARY'S Hosp., LONDON, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

The aim of this study was to assess whether a goal based questionnaire identifies different information from standard questionnaires for women with lower urinary tract symptoms.

Background:

In clinical practice, quality of life (QOL) questionnaires are used to assess the impact of lower urinary tract symptoms on patient QOL as well as the treatment outcomes. However there is little evidence to demonstrate the relationship between QOL questionnaires and patients' expectations and what constitutes significant change [1].The Self Assessment Goal Achievement (SAGA) questionnaire was designed to address the treatment goals relating to overactive bladder and other lower urinary tract symptoms. In addition to the directed goals the SAGA questionnaire has the unique provision for the patient to document their self determined goals. To date the patient's expectations of treatment has been poorly investigated.

Methods:

Women who attended the urodynamics and urogynaecology clinics at a tertiary Urogynaecology centre over 3 months were recruited to the study. In addition to the King's Health Questionnaire they were asked to complete the new SAGA questionnaire which provides a list of seven fixed treatment goals related to overactive bladder symptoms and voiding dysfunction. The patient documented the importance of achieving that goal with a score ranging from 0 to 5. In addition there was space for five free text patient determined goals which they prioritise with a score ranging from 0 to 5. Finally, the woman was asked to prioritise five most important goals (either fixed or patient determined) in order of importance. The clinician then discussed these goals and advised specific measures and treatments to achieve them.

Results:

One hundred and seventy eight women with overactive bladder symptoms were recruited to the study. The mean age was 53 (range 25–80) and 92% of women (164 women) had urodynamics. 48%(79 women) were diagnosed with detrusor overactivity (DO), 14%(23 women)with urodynamic stress incontinence (USI), and 19%(32 women) with both DO and USI. 3% (4 women) had painful bladder syndrome and 16% (26 women) of urodynamics were inconclusive.

The patient documented treatment goals in the SAGA questionnaire were categorised according to the patient's symptoms and quality of life domains

Table 1- Categories of patient documented treatment goals according to the patient's symptoms.

Treatment goals according to the patient Symptoms	Patients most important goal
Treatment of Urge Urinary incontinence	27.7%
Treatment of day time frequency	24.4%
Reduction of urgency	19.3%
Treatment of nocturia	16.8%
Treatment of stress urinary incontinence	7.6%
Treatment of others	4.2%

Table 2: Categorisation of self determined free text goals according to KHQ quality of life domains

KHQ - QOLdomains	Percentage of patient's most important goal	Examples of free text
Symptom severity measures	22%	'To be dry'
		'Not to wear pads';'Not to wear a pad just in case.'
		Not to take medication
		To be able to drink beverage/drink more fluids
		Not to smell of urine
Social Limitations	18.6%	Able to watch movie
		Able to travel without having to stop
		Go out socially and enjoy
		I want to enjoy life
Sleep and Energy	16.9%	Like to have a good night sleep.
		To sleep better
Role limitation	10.2%	Able to do shopping
		Able to work without interruptions
		Able to go to work without having to stop and go to the toilet
Personal relationship	8.5%	Having sex without fear of leakage
		To make love without the fear of leakage
		To have intercourse again
Emotions	3.4%	Not to worry about finding a toilet
		I want to be like my friends
		Fear of leakage
		Feel grumpy
Others	20%	Relating to prolapse, bladder pain etc.

Conclusion:

In terms of symptoms, cure of urge urinary incontinence appeared to be the most common treatment goal (28%), followed by daytime frequency (24.4%) in the group of women studied. This is in keeping with detrusor overactivity being the most common urodynamic diagnosis in our study group. In relation to quality of life domains, the most common treatment goal was linked to symptom of severity measures (22%). The Self assessment Goal achievement (SAGA) questionnaire allows an insight into patient's own goals using fixed and self determined areas and what they wish to achieve from treatment.

Reference:

1.BJOG. 2004 Jun;111(6):605–12.

Presentation Number: 102

THE EFFECTS OF VAULT DRAINAGE ON POST OPERATIVE MORBIDITY AFTER VAGINAL HYSTERECTOMY FOR BENIGN GYNAECOLOGICAL DISEASE: A PROSPECTIVE RANDOMISED STUDY

A. DUA[1], A. GALIMBERTI[1], M. SUBRAMANIAN[2], G. POPLI[3]; [1]Sheffield Teaching Hosp. NHS Fndn. Trust, Sheffield, United Kingdom, [2]Royal United Hosp. Bath NHS Trust, Bath, United Kingdom, [3]Univ. of Sheffield, Sheffield, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate the efficacy of vault drains in reducing the risk early post-operative morbidity following VH.

Background:
Though vaginal hysterectomy (VH) is a commonly performed procedure and has lower risks as compared to abdominal hysterectomy, it is still associated with high incidence of vault hematomas (25–40%). Vault hematomas are associated with significant febrile morbidity, post-operative haemoglobin drop, need for blood transfusion, readmission to hospital and length of hospital stay (1). Prophylactic measures to reduce hematomas such as use of vault drains, may help to reduce the post-operative morbidity but has not been evaluated in context of VH.

Methods:
This was a prospective randomised study and was conducted in a tertiary referral gynaecology unit in the UK. The study had local research and ethics committee approval. Women who underwent vaginal hysterectomy for a benign condition and agreed to participate were randomised to either have a drain (non-suction) or no drain. Randomisation was carried out using a double sealed envelope. The sample size was calculated based on a reported incidence of febrile postoperative morbidity of 30%. In order to demonstrate a 50% reduction in the treatment group, 135 women were required in each arm of the study (α=0.05, β=0.80 1:1 randomisation ratio).The envelope was opened prior to vault closure. The surgical technique and post-operative care, use of vaginal pack and urinary catheters were not altered. The primary outcome was reduction in postoperative febrile morbidity and secondary outcome measures were postoperative haemoglobin drop, need for blood transfusion, length of hospital stay and re-admission to hospital.

Results:
272 patients were included of which 137 were randomised to 'no drain' and 135 to have a drain. There was no difference in the mean age, BMI, parity and co morbidities and estimated blood loss (EBL) during surgery in the two groups. Post operatively there was no difference noted in the febrile morbidity (defined as one or more episode of pyrexia ≥37.5c), haemoglobin drop and need for blood transfusion and length of stay in both groups (Table 1)

Conclusion:
The use of vault drain at vaginal hysterectomy does not reduce the post-operative morbidity of the procedure, therefore routine use of drain is not recommended.

References:
1. Br J Obstet Gynaecol.1998;105(2):211–5

Table 1: Results in 'drain' and 'no drain' Groups

	No Drain (n=137)	Drain (n=135)	p value
Fever (n)	34	33	1.0
Mean Temperature	37.7	37.8	0.64
Mean haemoglobin drop	1.76	1.79	0.84
Blood transfusion	6	5	0.78
Length of stay (nights)	3.43	3.44	0.93
Readmission to hospital	2	1	0.57

Presentation Number: 103

URINARY RETENTION AFTER VAGINAL PROLAPSE SURGERY IS RELATED TO ANXIETY AND NOT TO THE PROLAPSE REPAIR ITSELF

R. A. HAKVOORT[1], M. M. LAKEMAN[2], A. VOLLEBREGT[1], M. Y. BONGERS[3], F. W. BOUWMEESTER[4], I. RUHE[5], J. P. ROOVERS[2];
[1]Spaarne Hosp., Hoofddorp, Netherlands, [2]Academic Med. Ctr., Amsterdam, Netherlands, [3]Maxima Med. Ctr., Veldhoven, Netherlands, [4]Waterland Hosp., Purmerend, Netherlands, [5]Flevo Hosp., Almere, Netherlands.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate whether surgery related variables or non-surgery related variables, predict the occurrence of abnormal post void residual volumes (PVR) after vaginal prolapse surgery.

Background:
One of the most common complications directly related to prolapse surgery is the occurrence of abnormal PVR. The etiology of this complication is largely unknown.
Efforts to identify risk factors for the occurrence of abnormal PVR could result in a reduction of the occurrence of this complication and could also optimize individual preoperative counselling as well as treatment protocols. We performed a prospective multi-centre study to identify such factors.

Methods:
Prospective observational cohort study in five teaching hospitals and one non teaching hospital in the Netherlands. We included women older than 18 years undergoing vaginal surgical correction for

symptomatic pelvic organ prolapse. The following characteristics were collected: patient characteristics, surgery related parameters, postoperative pain (assessed using VAS scales), micturition symptoms (assessed using UDI domain scores), postoperative situationally induced anxiety level and preoperative background level of anxiety (assessed using the spielberg STAI inventory). We defined abnormal PVR as a postvoid residual volume higher than 150 ml as measured by a bladderscanning device on the morning of the first operative day. This was the main outcome measure of the study.

To identify independent risk factors for the development of abnormal post void residual volumes (PVR) first the association between each variable and abnormal PVR was quantified using univariable logistic regression analysis. Subsequently, predictors that were univariable associated with the outcome (univariable p-value<0.15) were included in a multivariable logistic regression model with stepwise backward selection using SPSS 18.0 (SPSS Statistics UK, SPSS Inc, Chicago, IL (20).

Results:

A number of 342 patients were included. Univariable analysis showed that higher parity, more pain, higher postoperative situational anxiety level, higher preoperative baseline anxiety level, higher UDI pain, higher UDI prolapse, anterior colporraphy and the placement of suburethral sutures (Kelly) were associated with abnormal PVR. To identify the most important predictors of abnormal PVR, these factors were included in a multivariable logistic regression model. Using stepwise backward selection a final model with the best predictors for abnormal PVR was constructed. Anterior colporrhaphy, parity, postoperative situational anxiety score and UDI pain were the factors which were included in this multivariable model. After multivariable analysis postoperative situationally induced anxiety appeared to be the only statistically significant predictor.

Conclusion:

The occurrence of abnormal PVR after vaginal prolapse surgery is mainly predicted by postoperative anxiety level and not by prolapse surgery related parameters. This finding provides a new insight in the etiology of abnormal PVR and is helpful in developing new strategies to prevent this complication.

Table: Risk factors for the development of abnormal PVR with calculated odds ratios, significance levels and regression coefficients

	Univariable analysis				Multivariable analysis			
	OR	95% CI	P	B	OR	95% CI	p	β
Parity	1.3	1.−1.8	.06	0.28	1.34	0.9–1.9	0.09	0.29
Pain sore on first postoperative day	1.0	1.0–1.0	0.01	0.02				
Postoperative situational anxiety level (State)	1.0	1.0–1.1	0.01	0.04	1.03	1.0–1.1	<0.05	0.03
Preoperative baseline anxiety level (Trait)	1.0	1.0–1.1	0.11	0.02				
UDI pain domain score	1.0	1.0–1.0	0.11	0.01	1.01	1.0–1.0	0.06	0.01
UDI prolapse domain score	1.0	1.0–1.0	0.06	0.01				
Anterior colporraphy	2.3	1.1–4.7	0.02	0.83	2.08	0.9–4.8	0.09	0.73
Suburethral (Kelly) sutures	4.2	1.4–12.4	0.01	1.4				

Tests performed: Univariable and multivariable logistic regression analysis with stepwise backward selection.
OR = Odds ratio
CI = Confidence interval
P = p-value
β = regression coefficient

Presentation Number: 104

TREATMENT FOR PAINFUL BLADDER SYNDROME: META-ANALYSIS

P. K. MATSUOKA, J. M. HADDAD, A. M. PACETTA, E. C. BARACAT;
Univ. of Sao Paulo, Sao Paulo, Brazil.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To assess the effectiveness of intravesical treatment for Painful Bladder Syndrome.

Background:

Painful Bladder Syndrome is a chronic disease that is characterized by bladder pain, urinary frequency, urgency and nocturia. Its etiology is still uncertain. Treatment options for these patients are purely empirical and symptomatic.[1] However, it is suggested that multifactorial factors are involved in the genesis of the syndrome.[2] Macroscopic modifications of the vesical mucosa associated to

deficiencies in its components, guide researches aiming a definitive treatment.[2–3] In these context, intravesical treatments assume a great importance.

Methods:

A systematic review of the literature was performed, searching PubMed® and Lilacs® Database until 2010 October, 11th. We used a high sensibility and low specificity search strategy, formulated from key-words, synonyms for painful bladder syndrome or interstitial cystitis. Selection criteria of the studies included only randomized controlled trials in the review if they had recruited participants with a clinical diagnosis of Painful Bladder Syndrome and if at least one arm of the trial was a treatment with an intravesical preparation. The primary outcomes were the effect on symptomatology and on urodynamics parameters. Secondary outcomes included symptomatic response to treatment, quality-of-life assessment and adverse events. Data collection and analysis were performed by two reviewers independently. All selected studies were classified according the Levels of Evidence Scale of Oxford and Jaddad scale. After the systematic review, a meta-analisys with comparable outcomes were performed. The results were presented as weighted mean difference for quantitative variables and as odd ratio for qualitative variables, both with 95% of confidence interval.

Results:

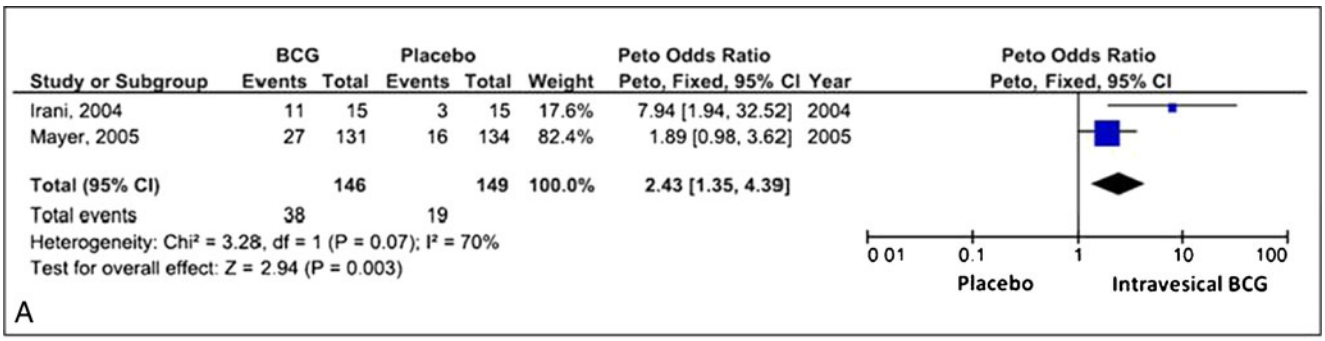
Initially, 770 studies were identified by the formulated search strategy. But only eight eligible trials filled the necessary prerequisites for the systematic review. Seven trials compared a drug instillation with placebo instillation and one compared instillation of Pentosan Polysulphate with via oral Cyclosporine A. Altogether, the review included trials of six different types of intravesical instillation: Resiniferatoxin, Dimethyl Sulfoxide, BCG, Pentosan Polysulphate, Oxybutynin, Alkalinized Lidocaine. All the included studies were classified as 1b according to Levels of Evidence Scale of Oxford. Among the studies, according to Jaddad Scale one was grade 4, three were grade 3, three were grade 2 and one was grade 0. The outcome measures were evaluated by a large variety of instruments. However, there were two studies that evaluated intravesical Bacillus de Calmette-Guerin (BCG) with two similar parameters to outcome measures. So in these case, we performed two meta-analysis calculus with common variables of both studies and with the same scale of quantification (Fig. 1).

Conclusion:

BCG showed difference in diminishing urinary frequency and an improvement in the global response to treatment. Although, the evidence base for treating Painful Bladder Syndrome using intravesical preparations is limited and the potential for meta-analysis was reduced by variation in the outcome measures used.

References:

1) British Journal of Urology 1997;79(2):168–71. 2) Journal of Urology 2000 Jun; 163(6):1818–22. 3) Urology 2002; 59 (Suppl. 5A):18–24.



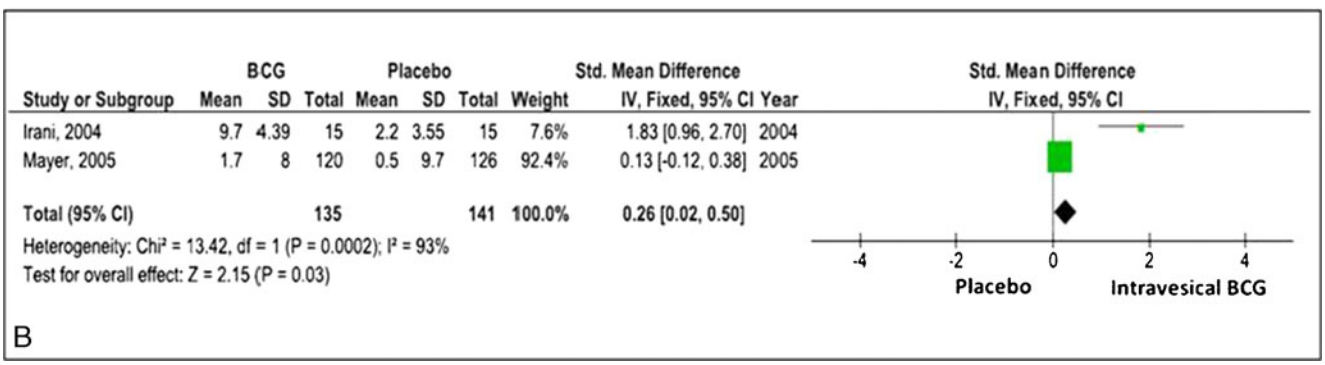


Figure 1. Estimative of Response after intravesical Bacillus Calmette- Guerin A - Global Response Assessment; B- Mictional Frequency in 24 h.

Presentation Number: 105

THE PREVELANCE OF URINARY CATHTERIZATION IN WOMEN AND MEN WITH MULTIPLE SCLEROSIS

S. T. MAHAJAN[1], R. A. MARRIE[2];
[1]Case Western Reserve Univ., Shaker Heights, OH, [2]Univ. of Manitoba, Winnipeg, Canada.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To determine the rates of catheter use among a large sample of community-dwelling men and women with multiple sclerosis (MS) and associations between catheter use, disease severity, gender and quality of life (QoL).

Background:
Lower urinary tract dysfunction is common men and women with multiple sclerosis (MS) . Among MS patients, 50–80% report symptoms of urinary retention and/or incontinence during their disease course. Although urinary catheterization is commonly used, widely available and minimally invasive, the numbers of MS patients who utilize this therapy remains unknown.

Methods:
After obtaining IRB exemption, results from the Fall 2005 North American Research Committee On Multiple Sclerosis (NARCOMS) survey were reviewed. The NARCOMS Registry is the largest of its kind internationally, with more than 18,500 active participants diagnosed with MS. Responses to the Fall 2005 questionnaire, including the Urogenital Distress Inventory (UDI-6), the Short Form-12 QoL inventory, the Patient Determined Disease Steps (PDDS) measuring physical disability, and history of prior urologic evaluation and treatment were reviewed for this analysis. Data were analyzed using descriptive statistics, the chi-square and Student's *t*-tests, analysis of variance, and multivariate logistic regression, allowing associations with demographic information and QoL measures.

Results:
Of 16,858 surveys mailed, 9702 (58%) responses were returned. Any respondents with prior major bladder surgery (conduit, diversion or augmentation) were excluded. Respondents were primarily white (92.9%), women (75.3%), with an average age at MS onset of 30.2 (SD 10.0) years. Of our 9676 respondents, 2514 (26%) reported using some form of urinary catheterization, including 751 males (32%) and 1763 females (25%). Males were significantly more likely to report a history of catheter use than females (32% versus 24%, $p<0.001$). When divided temporally, 1091 (11%) of all respondents reported current catheter use, while 1423 (15%) reported past use only (Table 1). Intermittent self-catheterization was most commonly used (ISC, 81%), followed by transurethral foley catheterization (TFC, 43%) and suprapubic catheterization (SPC, 8%). Males preferred indwelling catheterization methods over females, with TFC used by 47% of males versus 41% of females ($p=0.003$) and SPC utilized by 12% of males and only 6% of females ($p<0.001$). Overactive bladder symptoms were more severe in catheterizing patients (all $p<0.001$, Table 2). Urologic evaluation and treatment rates were low, with only 44% reporting evaluation by urology, 21% urodynamic testing, 26% post-void residual screening and 37% treatment with an anticholinergic medication. Patients who catheterize were significantly more likely to be treated with anticholinergic medications (55% versus 30%, $p<0.001$), particularly older medications, such as oxybutynin and tolterodine, while very few patients had undergone sacral neuromodulation (3%) or intra-detrusor botulinum A toxin injection (9%).

Catheterizing patients tend to have significantly longer disease duration (mean 17.1 versus 12.1 years, $p<0.001$) and greater physical disability as gauged by their PDDS scores (mean 4.9 versus 3.1, $p<0.001$), as well as significantly lower QoL scores in all components of the SF-12 (all $p<0.001$).

Conclusions:
This study is the first of its kind to demonstrate the significant rates of urinary catheterization in patients with MS. Although the development of voiding dysfunction and catheter use is common among patients with MS, rates of catheter use in this population was previously unknown. Our study demonstrates that 26% of patients with patients with MS catheterize for urinary symptoms, 11% currently and 15% in the past. Despite its necessity, urinary catheterization is associated with reduced QoL, increased physical disability and longer disease duration among catheter-dependent patients with MS.

Table 1. Catheter use in MS study population based on gender and type of catheter.

Catheter Type	Overall (*n*=9676)	Male (*n*=2386)	Female (*n*=7290)	p value
Catheter use (any)	2514	751 (32%)	1763 (24%)	<.001
Intermittent Self-Catheter	2042 (81%)	623 (83%)	1419 (81%)	.147
Current	765 (38%)			
Past	1277 (62%)			
Foley Catheter	1076 (43%)	355 (47%)	721 (41%)	.003
Current	208 (19%)			
Past	868 (81%)			
Supra-Pubic Catheter	195 (8%)	87 (12%)	108 (6%)	<.001
Current	118 (61%)			
Past	77 (40%)			

Table 1. Overactive bladder symptoms based on catheter use.

Presence of OAB symptoms, evaluation/treatments	Catheter Use Yes (n=2514)	Catheter Use No (n=7162)
OAB Symptoms (>1 score on UDI-6)	1831 (73%)	5133 (73%)
Frequency	1729 (69%)	4746 (66%)
Urgency	1243 (49%)	3361 (47%)
Activity with Leakage	1465 (58%)	3791 (53%)
Small Leakage	1721 (68%)	3768 (53%)
Emptying	886 (35%)	1703 (24%)
Abdominal Pain	1826 (73%)	5430 (76%)
Nocturia		

OAB: Overactive Bladder

Presentation Number: 106

DIFFERENT EPISIOTOMY TECHNIQUES AND ASSOCIATION TO PERINEAL PAIN -A PROSPECTIVE STUDY

K. FODSTAD[1], K. LAINE[1], A. SCHMIDTKE[2], A. C. STAFF[1]; [1]Oslo Univ. Hosp., Ullevaal, Dept. of Obstetrics, Oslo, Norway, [2]Faculty of Med., Univ. of Oslo, Oslo, Norway.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objectives:

The primary study aim was to

a. assess episiotomy techniques performed at Oslo University Hospital, Ullevål.

Secondary aims were to compare the different techniques in relation to:

b. postpartum perineal pain

c. sexual function 3 months after delivery

d. anal and urinary incontinence 3 months after delivery

Background:

When episiotomy is clinically indicated during labour, a mediolateral technique has been the procedure of preference in Western Europe. Midline episiotomy, being a known risk factor for obstetric anal sphincter injuries (OASIS), is less often used. Lateral episiotomy technique is rarely addressed in international studies, but is nevertheless practiced in some European countries. Lateral episiotomies have been suggested to cause more postpartum perineal pain compared to other types of episiotomies, but this has to our knowledge previously never been systematically studied.

Methods:

Within 3 days after delivery, women, where episiotomy was performed, were asked to participate in this prospective study from March 2010 through February 2011. Following informed consent, the episiotomy technique was assessed by the MD/PhD-student during a clinical examination with the postpartum women in the lithotomy position. A transparent plastic film was placed on the perineum and the line of the episiotomy scar was drawn using a permanent marker pen. The episiotomy was measured in length, incision point and angle from the (para)sagittal plane. Clinical variables were collected from pregnancy health certificates and electronic medical records. The participants scored perineal pain on an 11-point VAS-scale. A questionnaire focusing on sexual function, anal and urinary incontinence as well as perineal pain was distributed 3 months after delivery.

Results:

Two hundred and eighty four women were recruited during the 12 study months. Most participants were primipara (84%). Gestational age was 36–42 weeks.

a. Episiotomy measurements:

Based on the measurements, we categorized the episiotomies into four groups:

1. Midline episiotomy: an incision commencing less than 7 mm from the posterior commisure, angled 20 degrees or less from the (para)sagittal plane (13/284 participants)
2. Mediolateral episiotomy: the incision commencing less than 7 mm from the posterior commisure, angled 21–50 ° from the (para)sagittal plane (58/284 participants)
3. Lateral episiotomy: the incision commencing 7–41 mm from the posterior commisure, angled 21–50° (147/284 participants)
4. Incorrect/not-definable episiotomy: incision point 7–41 mm from the posterior commisure, angled less than 20° or above 50° (66/284 participants)

		Distance to the (para)sagittal plane	
		0–6 mm (n= 75)	*7–41 mm (n= 209)*
Angle of episiotomy	**Degrees**	**%**	**%**
	0–20°(n=22)	17.3	4.3
	21–50°(n= 205)	77.3	70.3
	51–91° (n=57)	5.3	25.4

Physicians performed significantly longer episiotomies than midwives (mean 34 mm vs. 27 mm, $p<0.005$), but there was no significant difference in mean episiotomy angle between the professions (41° vs. 39°, $p=0.135$). Midwives favoured mediolateral technique (60%), whereas physicians favoured lateral technique (60% lateral vs. 40% mediolateral, $p=0.03$).

b. Postpartum perineal pain perception

A hundred and ninety one participants scored perineal pain on an 11-point VAS scale the first day after delivery. Most participants (44%) reported a moderate VAS score (4–6), whereas 38% reported a low VAS score (0–3). Few (18%) reported a high VAS score (7–10). There was no significant difference in pain

perception between instrumental and spontaneous deliveries. Nor any difference in pain perception between women with the longest versus the shortest episiotomies (63% vs. 66%, $p=0.4$). We found no association between different episiotomy techniques and level of perineal pain.

c-d. Sexual function, anal and urinary incontinence 3 months after delivery:

results will be presented at the IUGA meeting as not all questionnaires have been received.

Conclusions:

-Lateral and mediolateral episiotomies were the most frequent episiotomy techniques performed in our department. Midwives were more prone to the mediolateral technique, physicians to the lateral. Episiotomy angle did not vary significantly amongst professions whereas previous studies have documented the opposite. Focus on better episiotomy technique and systematically working towards reducing the OASR incidence rate in our department might be an explanation for less difference between accoucheurs than in other studies

-No major differences in postpartum perineal pain perception the first day after delivery between different episiotomy techniques

-Patient self-assessment 3 months postpartum will be reported at the IUGA meeting

Presentation Number: 107

REFERRAL PATTERNS FOR TREATMENT OF MESH/ GRAFT COMPLICATIONS IN THE U.S.; ARE THE PRIMARY SURGEONS REFERRING THEIR MESH COMPLICATIONS?

K. P. GOLD[1], J. DANFORD[1], R. M. WARD[1], D. H. BILLER[1], M. A. NIHIRA[2], L. H. QUIROZ[2], J. C. SLAUGHTER[1], S. A. SHOBIERI[2];

[1]Vanderbilt Univ. Med. Ctr., Nashville, TN, [2]Oklahoma Univ. Hlth.Sci. Ctr., Oklahoma City, OK.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

This study evaluates the referral patterns to tertiary care centers for the surgical management of mesh and graft complications. We hypothesize that the majority of patients referred to a tertiary care center were not referred by the primary surgeon who placed the mesh.

Background:

Historically, procedures for the correction of urinary incontinence and pelvic organ prolapse had reoperation rates approaching 30%. In an effort to improve outcomes, gynecologic surgeons began augmenting these repairs with a variety of graft materials including biologics and synthetics. The growth in the number of surgeries done for urinary incontinence and pelvic organ prolapse that involve the implantation of mesh or graft has led to an increase in the number of complications seen by specialists in the field of Female Pelvic Medicine and Reconstructive Surgery at tertiary care referral centers. The authors are unaware of data evaluating the referral patterns of women with complication from mesh or graft use in the repair of pelvic floor disorders.

Methods:

A retrospective case series of women requiring surgical revision of urogynecologic mesh between January 2004 and May 2009 was performed at two major medical centers in the U.S. All of the women had mesh or graft complications following surgery for pelvic organ prolapse or urinary incontinence. Records were reviewed to determine the source of referral, as well as patient demographics, procedure, and type of complication. Categories of referral included: continuation of care at the tertiary center at which the mesh or graft was initially implanted, referral from the outside surgeon who initially implanted the mesh or graft, referral from a secondary healthcare provider not involved in the initial surgery, and self-referral.

Results:

We identified 173 women with a mesh or graft complication requiring surgical intervention. The mean age was 55, median gravidity was 2, and median parity was 2. Referral patterns were as follows: 32.4% continued care at the tertiary care center where mesh or graft was initially placed, 19.1% referred from the outside surgeon who initially placed the mesh or graft, 42.2% from an outside secondary healthcare provider and 6.4% self-referrals. The most commonly reported complication was exposure of the mesh into the vagina (68.2%), followed by pain (36.4%), dyspareunia (33.5%), urinary incontinence (31.2%), vaginal discharge (27.2%), vaginal bleeding (27.2%), and recurrent pelvic organ prolapse (18.5%). Many of the patients had more than one complication.

Conclusions:

The majority (68%) of mesh/graft complications requiring surgical intervention at these two tertiary care centers were referred from an outside source, and, of those, 72% were referred by someone other than the implanting surgeon. Whether these women returned to the primary surgeon after the complication is not known, but these findings suggest mesh/graft complications may be underappreciated by the implanting surgeon. Most concerning is the delay to care of patients who are seen by multiple providers before reaching a specialist who can treat them.

Presentation Number: 108

COMPLICATIONS OF SYNTHETIC MATERIALS USED IN FEMALE PELVIC FLOOR SURGERY- POSSIBLE REASONS AND APPLICABILITY OF THE NEW IUGA-ICS CLASSIFICATION

K. ASHOK, E. PETRI;

Univ. of Greifswald, Greifswald, Germany.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

To analyze different complications of synthetic slings and meshes used in pelvic reconstructive surgery in terms of nature of complications and the possible reasons for their occurrence. To apply the new "IUGA-ICS classification of complications directly related to the insertion of prosthesis(meshes, implants, Tapes) and grafts in female pelvic floor surgery" to the list of complications and check its applicability, and give suggestions regarding possible improvements.

Background:

Use of alloplastic materials has resulted in unique complications and clinical scenarios witnessed by pelvic floor surgeon. It is important to be aware of all possible types and reasons for complications, in order to provide necessary information to the patients and to minimize them.

Materials and Methods:

This study is both retrospective and prospective analysis of the complications of alloplastic materials in female pelvic floor surgery managed at a tertiary referral center. Data on parity, weight, type of complication, time interval between insertion of the prosthesis and the onset of symptoms of complication, type and nature of prosthesis, and the management process were documented. In order to evaluate possible reasons for the complications, additional data on presence or absence of para-vaginal defects, description of prosthesis position in relation to lower urinary tract, shrinkage or prominence of prosthesis, and intra-operative nature of alloplastic material were collected for analysis.

Results:

429 cases of complications of alloplastic materials managed surgically from the year 2003–2010 were analyzed. Of all the complications, overactive bladder constituted 50%, lower urinary tract obstruction 41%, vaginal exposure19%, and pain constituted 16%. 388 complications were directly related to insertion of midurethral slings. Infection, fistulae, urinary tract penetration, groin/thigh pain were other complications. Less common, but important complications were dyspareunia of the partner (with two cases of penile injury), urine loss during intercourse and foreign body sensation in the vagina. In our study abnormal positioning of the slings(48% of all sling complications had abnormal position) was the most common reason for complication, followed by use of midurethral sling in patients with paravaginal defects(44%), overcorrection or excessive tensioning of the slings (18%), and use of slings in women with previous anti-incontinence surgery (21%) . The new IUGA-ICS classification could be applied to most of the types of complications, a notable exception being denovo development of overactive bladder. Also category 4B of IUGA-ICS classifications encompasses a wide clinical variety of complications and may need reconsideration.

Conclusion:

Most of the complications of alloplastic materials used in female pelvic floor surgery result from surgical mistakes or wrong indications like abnormal positioning of slings, use of slings in patients with paravaginal defects, excessive tension on the slings and use of slings in patients with previous pelvic floor repairs. The new IUGA-ICS classification on complications has good general applicability; few minor changes may be useful in the future.

References:

1.Int Urogynecol J 2011; 22(1): 3–15
2.BJU Int. 2004 Jul;94(1):110–3
3.Int Urogynecol J 2010 Mar;21(3):261–70

Table: Complication of alloplastic materials used in female pelvic floor surgery

2 Complications of alloplastic materials in pelvic floor surgery—total number 422

	Nature of Complication	Number	Percentage	classification
1	Overactive bladder	210	49.76	**?**
2	Lower urinary tract Obstruction	177	41.94	**4B/Site?**
3	Vaginal exposures	79	18.72	**2B or 3B/S1 or S2**
4	Pain	67	15.87	**1Be/S1 or S2 or S4**
5	Dyspareunia	27	6.39	**1Bc/S1 or S2?**
6	Mesh contraction (symptomatic& palpable sling/mesh)	30	7.1	**1A or 1B/S1 or S2**
7	Infection of the material	32	8	**1,2,or 3 C/D**
8	Contralateral compartment defects	14	3.31	**Not applicable**
9	Vesico vaginal fistula	13	3.08	**4B/S1 or S2**
10	Intra-operative bladder injuries	10	2.36	**4A/S3**
11	Groin/upper thigh pain	11	2.6	**6Be/S4**
12	Post operative hematoma	9	2.13	**7A/S3**
13	Vaginal bleeding/ discharge	12	2.84	**1B/S1 or S2**
14	Urethral penetration	8	1.89	**4B/S1**
15	Foreign body sensation in vagina	9	2.13	**?/S1 or S2?**
16	Bladder penetration	10	2.36	**4B/S3**
17	Husband penile laceration and pain	6	1.42	**Not applicable**
18	Skin infection and abscess	6	1.42	**6C or D/S4**
19	Retropubc abscess	3	0.71	**?**
20	Necrotizing fasciitis	3	0.71	**7B/S0**
21	Urine loss during intercourse	3	0.71	**Not applicable**
22	Urethro-vaginal fistula	2	0.47	**4B/S1 or S2**
23	Urethral injury	1	0.23	**4A/Site1**
24	Bowel injury	1	0.23	**5A/S5**
25	Rectal injury	1	0.23	**5B/S3?**
26	Recto-vaginal fistula	1	0.23	**5B/S1 or S2?**

Presentation Number: 109

A PROSPECTIVE MULTICENTRE STUDY OF ADJUSTABLE SINGLE-INCISION MINI-SLING (AJUST®) IN MANAGEMENT OF STRESS URINARY INCONTINENCE IN WOMEN: 1-YEAR FOLLOW-UP STUDY

M. ABDEL-FATTAH[1], W. AGUR[2], M. ABDEL-ALL[3], K. GUERRERO[4], M. ALLAM[5], A. MACKINTOSH[6], A. MOSTAFA[6], M. YOUSEF[7];

[1]ABERDEEN ROYAL INFIRMARY, ABERDEEN, United Kingdom, [2]CROSSHOUSE Hosp., KILMARNOCK, United Kingdom, [3]BORDERS & GENERAL Hosp., MELROSE, United Kingdom, [4]SOUTHERN GENERAL Hosp., GLASGOW, United Kingdom, [5]WISHAW GENERAL Hosp., WISHAW, United Kingdom, [6]Univ. OF ABERDEEN, ABERDEEN, United Kingdom, [7]INVERCLYDE ROYAL Hosp., GREENOCK, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To determine whether adjustable single-incision mini-slings (SIMS; Ajust®) are safe and effective in the management of female stress urinary incontinence (SUI) at 12 month follow-up.

Background:

Single-Incision Mini-slings (SIMS) were first introduced in 2006 with the aim of reducing peri-operative morbidity, by avoiding both the retropubic and groin muscle trajectories, while maintaining the efficacy of standard mid-urethral slings (SMUS). 'Ajust'® (C. R. Bard, Inc., Murray Hill, New Jersey, USA) is a novel adjustable SIMS that has been recently introduced into clinical practice. However, unlike previous SIMS, it provides robust insertion into the obturator internus muscle/membrane and allows a full post-insertion adjustment as with SMUS. As yet no studies have reported on its medium-term efficacy at 12 months. Furthermore it has the potential to be performed under local anaesthesia (L.A), potentially reducing the operative morbidity and recovery time. However, the acceptability and feasibility of these procedures under L.A in women is scarcely reported.

Methods:

A prospective cohort study in six centres in Scotland was completed. 90 women, representing the early learning curve cases for the surgeons involved, underwent adjustable SIMS for SUI. Procedures were performed using a standardised technique; cystoscopy was performed for all women. The last 45 women in the group were offered the procedure under LA. Intra-operative data collected included: operative time, complications, pain assessment (L.A group) using 10 pt Likert scale at 'end of dissection' and 'second trochar insertion'. Post-operative pain scores and voiding assessment were recorded. Primary outcome was patient-reported success rate at 12 months using "patient global impression of improvement" (PGI-I). Secondary outcomes included peri-operative complications, feasibility/acceptability of SIMS to be performed under LA and comparison of postoperative pain and recovery time between G.A and L.A groups.

Results:

3 and 12 month follow up results are reported in Table 1. 71% (32/45) of women accepted the LA option and 97% (31/32) were completed using our LA protocol. Significantly lower rates of blood loss (p=0.025) and postoperative voiding difficulties (p=0.026) were seen in the LA group. There was no organ damage or requirement for blood transfusion. In the LA group the median (IQR) intra-operative pain scores were 0.0(0.0, 1.0) and 2.0(0.0, 4.8) at "end of dissection" and "following trochars insertion" respectively. There was no difference in post-operative pain scores between G.A and L. A groups (Table 2). Median time to return to normal activities in the L.A group was 4.5 days (2.5, 8.5) compared to 5 (2, 14) in the G.A group (p=0.992). Re-operation rate for SUI was 6% at 12 month.

Conclusions:

SIMS Ajust© under LA is feasible and acceptable to the majority of women with no significant difference in postoperative pain or return to normal activities following LA versus GA. It appears to be a safe procedure, associated with low intra & postoperative pain scores and 80% patient-reported success rate at 12 month follow-up.

This study has a number of strengths: it is a multicentre prospective study of a relatively large cohort of women and with the longest reported follow-up for this procedure. Assessment was done using validated questionnaires. A potential limitation is that this study represents the early learning curve cases for the surgeons; this may explain the relatively high re-operation rate of 6% at 12 months. There is a potential selection bias; although all women admitted for MUS were offered the procedure, those accepting are likely to be well motivated for new interventions. Nevertheless, these results would be extremely helpful in patient counselling regarding success rates during the surgeons' learning curve. Furthermore, these results are least likely to be reported in randomised trials where completion of the learning curve is usually a prerequisite.

A randomised trial comparing adjustable SIMS to standard MUS, with long follow-up and health-economic evaluation, is essential before being incorporated into routine clinical practice.

Table 1: Patient-reported and Objective Outcomes at 3–12 month

PGI-I	Pre-operative	3 month	12 month	p
Success		74(82.2)	72(80)	0.136
Improved		6(6.7)	5(6)	
Failed		10(11.1)	13(14)	
ICIQ-SF	Pre-operative	3 month	12 month	
ICIQ-SF Score: Median (IQR)	15.00(12.0.17.0)	0.0(0.0,3.0)	0.0(0.0,5.0)	<0.001
Improvement in ICIQ-SF Score: Mean ± SD		11.8±5.2	11.0±5.7	
ICIQ-VAS: Median (IQR)	7.0(6.0,8.0)	0.0(0.0,0.0)	0.0(0.0,1.0)	
Cough Stress Test		*n*=85		
Positive		3(4)		
Negative		78(92)		
Missing		4(4)		

ICIQ-SF = International Consultation on Incontinence Questionnaire; Short Form VAS = Visual Analogue Scale

Table 2: Post operative pain scores using 10 pt Likert scale: Median (IQR)

Time point	Whole group	G.A	L.A	p
30 min	**0(0,0)**	**0(0,0)**	**0(0,0)**	**0.947**
3 h	**0(0,0)**	**0(0,0)**	**0(0,0)**	**0.565**
At discharge	**0(0,0)**	**0(0,1)**	**0(0,0)**	**0.254**

Presentation Number: 110

EFFECT OF A MODIFIED SURGICAL TECHNIQUE FOR THE POSITIONING OF TVT-O ON POST-OPERATIVE PAIN

G. A. TOMMASELLI[1], A. D'AFIERO[2], C. DI CARLO[1], C. FORMISANO[1], A. FABOZZI[1], C. NAPPI[1];
[1]Univ. of Naples Federico II, Naples, Italy, [2]Ospedale S.Maria della Pietà, Casoria, Italy.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To compare a modified surgical TVT-O technique with the standard procedure on post-operative groin pain and analgesic use.

Background:
TVT-O is wildey used for the treatment of female stress urinary incontinence with cure rates similar to retropubic TVT and limited complications (1). A drawback of this technique is post-operative and chronic groin pain. The source of post-TVT-O groin pain is not clear and may be related to surgical technique (dissection, insertion of the needles) or to the tape itself (passage through the muscles, foreign body reaction). Recently, a new device with a shortened tape was released in order to avoid extensive tape passage and residue into muscular and aponeurotic tissues (2). Along with this new device, some modifications to the technique to reduce invasiveness were also introduced (limited dissection and a more medial trajectory of the introducer). Aim of this study was to compare the traditional TVT-O technique with the modified technique, using the same tape (TVT-O), on post-operative pain and analgesic use.

Methods:
Forty patients with SUI were randomly assigned to traditional (A, n=21) or alternate technique (B, n=19). Inclusion criteria were: SUI and age>40 years. Exclusion criteria were: previous surgical and/or pharmacological treatment of SUI, predominant or isolated urge incontinence, genital prolapse >= stage 2 according to PoP-Q system, and serious contraindications to surgical procedures. All patients underwent a preoperative clinical examination with PoP-Q scoring, urodynamics, PVR evaluation, and Hb levels determination. The traditional TVT-O technique was performed as previously described (3). Alternate technique differed from traditional TVT-O for two aspects: 1. during lateral dissection, perforation of the obturator membrane by the scissors and guide was avoided and 2. once the obturator membrane was perforated with the helical passer, it was slowly rotated whilst bony contact with the inferior pubic ramus was maintained at all time during insertion, thus ensuring a tight passage around the bony structure, with the tip of the passer finally exiting at the skin level 0.5–1 cm from the inguino-crural plicae, 2 cm above a line passing a the urethral external meatus. Intra- and post-operative complications, Δ hemoglobin levels, and operative times were recorded. Post-operative pain level was assessed using a VAS scale from 0 (absence of pain) to 10 (maximum pain possible) 12 and 24 h and 1 month after the procedure. Analgesics were administered on demand and the total number of vials was recorded.

Results:
Baseline patients characteristics (age, BMI, parity, urodynamic data, and type of anesthesia) were similar in the two groups. No intra-operative complication was observed, as well as significant differences in blood loss and mean operative times between the two groups. Post-operative pain VAS score was significantly lower 24 h after the procedure in group B (p=0.03), but not 12 h and 1 months after (p=0.08 and 0.09, respectively) (Fig. 1). The number of analgesic vials was not different in the two groups.

Conclusions:
The study is limited by the small sample. Nevertheless, it seems that the limited dissection used in the alternate technique may induce a reduction of post-operative pain, even though this reduction is not reflected by the need of less analgesia.

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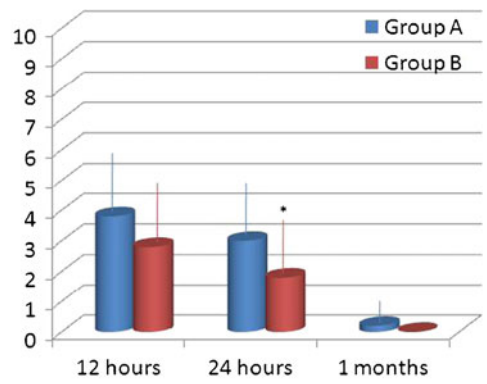


* P < 0.05

Presentation Number: 111

LONG TERM DURABILITY OF POLYDIMETHYLSILOXANE INJECTION FOR FEMALE STRESS URINARY INCONTINENCE CORRELATES WITH HISTOPATHOLOGY

G. M. GHONIEM[1], W. WUSTENBERG[2];
[1]Cleveland Clinic Florida, Weston, FL, [2]AlterNetMD Consulting, Farmington, MN.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objectives:
This review evaluates the 24 month durability of polydimethylsiloxane (PDMS) for treating SUI in women with previously documented successful treatment outcomes at 12 months and correlates it with tissue anchoring and stability of PDMS injection in a porcine histopathology study.

Background:
Stress urinary incontinence is a devastating condition that affects millions of women worldwide. Urethral bulking agents (UBA) have been widely used, however, long term durability varies between products as resporption, allergic reactions and migration can occur in some UBAs. PDMS elastomer implants (Macroplastique®) are soft, flexible, highly textured implants suspended in polyvinylpyrrolidone (PVP) hydrogel; they have been shown to be non-allergenic, cause minimal inflammatory reaction, do not migrate and have been found to be safe and effective.

Methods:
In an IRB-approved study, females diagnosed with SUI primarily due to ISD with successful PDMS treatment outcome at 12 months (≥1 Stamey grade improvement from baseline with a maximum of 2 treatments at 3 months, "Responders"), were followed for an additional year to assess their sustained therapeutic response. Outcome measures included Stamey grade, patient and physician assessments of improvement, Incontinence Quality of Life (I-QOL), pad weight and safety assessment. Separately, a 12 month porcine study replicating transurethral cystoscopic PDMS injections in human volumes was completed with local and distant organ histopathology.

Results:
67 of 75 12-month Responders were available at 24 months; 51% (34/67) had one treatment with mean volume injected of 4.5 mL. At 2 years, 84% of Responders (56/67) maintained Stamey improvement from 12 months; 67% were dry (45/67, Stamey 0). Of 33 dry Responders, 87% (33/38) maintained cure at 2 years. 41% (12/29) of those Responders who were improved but not dry were dry at 2 years. Both patient and physician assessments rated 85% dry or markedly improved from last treatment. Overall I-QOL scores and all subscales showed significant improvements from baseline ($p<0.001$). Mean pad weight reduction was significant at 24 months compared with 24 gm at baseline, 4 gm at both 12 and 24 months ($p<0.0001$). Clinical durability is supported by histopathology in the porcine study. Within 7 days, the PDMS bolus was fibrotically encapsulated with progression to a mature capsule by 3 months. By 30 days, fibrotic infiltration of the bolus formed a collagen matrix between and around individual PDMS implants further anchoring the implants within the tissue space. Minimal change was noted in the peripheral capsule from 3 to 12 months indicating long-term stability. There was no local or distant PDMS migration and no further histological changes through 365 days.

Conclusions:
Substantial and durable clinical results were sustained in 12-month Responders at 2 years with 67% dry and 84% maintaining significant improvement from 1 year earlier. The clinical durability of PDMS demonstrates its effectiveness as a viable long-term therapy for female SUI and is supported by long-term tissue anchoring and stability in histopathological results.

Presentation Number: 112

SEVERE URINARY INCONTINENCE: TVT, TVT-O OR TVT-S?

A. H. BIANCHI, L. M. OLIVEIRA, R. A. CASTRO, M. J. GIRAO, M. G. SARTORI, Z. I. JARMY-DI BELLA;
UNIFESP (Federal Univ. of São Paulo - Brazil), São Paulo, Brazil.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The objective of this study is to compare the efficacy of TVT, TVT-O and TVT-S midurethral tapes as surgical treatment for stress urimary incontinence (SUI) in patients with intrinsic sphincter deficiency (ISD), and/or previous anti incontinence surgeries.

Background:
The evolution of the female stress urinary incontinence management has followed the worldwide trend to adopt minimally invasive surgical procedures.
The first mid-uretral sling, TVT, dramatically changed the surgical treatment of SUI. Along the past 15 years, others devices using transobturator approach and more recently the single incision slings were developed in order to reduce the complication rates without decreasing post-operatory continence rates.

Methods:
137 patients who were performed the TVT ™(42), or TVT-O™ (45) or TVT-S™ (50) were included in study and analyzed prospectively. The follow-up was 12 months. All patients underwent pre-operatory clinical evaluation with pad-test and urodynamic test. Quality of life was also evaluated through the King's Health Questionnarie (KHQ). Clinical evaluation, pad-test and the KHQ were again performed 30, 90, 180 days and 1 years after the procedure. Urodynamic test was again performed 6 months and 1 year after the procedure. The criteria for objective cure was both negative pad test and normal urodynamic test. The criteria for subjective cure was patients considering themselves satisfied with the procedure.

Statistical analysis were performed by using Statistical Package for Social Sciences (SPSS v18.0). Statistical significance reached when $p<0.05$.

Results:

The groups are similar regarding demographic data as age, BMI, parity, vaginal deliveries, hormonal status and previous anti-incontinence surgeries. The subjective general continence rate (table1) and objective general cure (table 2) were similar in the 3 groups. Considering objective cure and ISD (VLPP<60) we also didn't find any statistical difference (table 3).

As regarding to previous anti-incontinence surgeries there was a significant difference between the groups. In the TVT-O group, patients with previous surgeries had a lower continence rate, comparing to those without previous surgeries. These were not observed in the TVT or TVT-S groups.

Table 1 Rates of subjective cure 1 year follow-up

			TVT	TVT-O	TVT-S	Total
Subjective Cure	Yes	N	40(95,2%)	42(93,2%)	46(92,0%)	128(93,4%)
	No	N	2 (6,7%)	3 (8,0%)	4 (6,6%)	9 (6,6%)
	Total		42	45	50	137

Chi ^{2}=0,391, p=0,822, Fisher p=0,911

Table 2 Rates of objective cure 1 year follow-up

			TVT	TVT-O	TVT-S	Total
Objective Cure	Yes	N	38(90.5%)	40(88,9%)	44(88,0%)	12(89,1%)
	No	N	4 (9,5%)	5 (11,1%)	6 (12%)	15(10,9%)
	Total		42	45	50	137

Chi ^{2}=0,145, p=0,930, Fisher p=0,941

Table 3 Objective Cure and ISD

		Objective Cure			
	ISD	Yes	No	Total	P
TVT					
	No	18(90%)	2(10%)	20	0,608
	Yes	20(90,9%)	2(9,1%)	22	
TVT -O					
	No	27(90%)	3(10%)	30	0,651
	Yes	12(80%)	3(20%)	15	
TVT-S					
	No	34(89,4%)	4(10,6%)	38	0,621
	Yes	10(83,3%)	2(16,7%)	12	

Fisher

Table 4 Previous anti-incontinence surgery and objective cure

		Objective Cure			
	Previous anti-incontinence surgery	Yes	No	Total	P
TVT					
	No	22 (91,6%)	2 (8,3%)	24	0,297
	Yes	16 (88,8%)	2 (11,1%)	18	
TVT -O					
	No	30 (93,7%)	2 (6,26%)	32	0,047
	Yes	10 (76,9%)	3 (23,7%)	13	
TVT-S					
	No	33 (83,8%)	5 (13,1)	38	1,00
	Yes	11 (91,6%)	1 (8,3%)	12	

Fisher

Conclusions:

We observed in our study that the 3 approaches of miduretral tapes (retropubic, transobturator and single incision sling) have reached similar objective and subjective cure rates in 1 year follow-up, independent of pre-operatory urodynamic's intrinsic sphincter deficiency. Otherwise in the transobturator approach, patients with previous failure had a lower continence rate, comparing to those without previous surgeries. These were not observed in the retropubic approach and single incision slings.

Presentation Number: 113

TRANSOBTURATOR TAPE FOR FEMALE STRESS URINARY INCONTINENCE: WHAT HAPPENS WHEN YOUR PATIENT DESCRIBES URINARY STRESS INCONTINENCE AT THE ONE MONTH FOLLOW UP

H. F. BRAUN[1], C. RONDINI[1], J. ALVAREZ[2], M. ESCOBAR[2]; [1]UGCM&RN Hosp. Padre Hurtado, Facultad de Med. Univ. del Desarrollo Clinica Alemana/Clinica Santa Maria, Santiago, Chile, [2]UGCM&RN Hosp. Padre Hurtado, Facultad de Med. Univ. del Desarrollo Clinica Alemana, Santiago, Chile.

Consent obtained from patients: Not Applicable

Level of support: Investigator initiated, no external funding

Work supported by industry: No

Objective:

The objective of this paper is to evaluate the natural evolution of those patients who continue incontinent after 1 month surgery and identify risk factors that could predict failure.

Methods:

We performed a retrospective analysis of 1211 patients who underwent a TOT procedure between January 2009 and December 2010, in which the sling passes from the obturator foramen from the outside to the inside. We identified those patients who

presented urinary incontinence at 1 month follow up and were followed at 3 months intervals for 1 year. We then analyzed how long it took for them to become dry without the use of physiotherapy, anticholinergic drugs or new surgery and analyzed the risk factors to stay incontinent after 1 year. Failure was defined as the loss of urine independently of the amount of effort.

Results:

Fifty nine out of the 1211 patients presented urinary incontinence at one month follow up. Seven of the 59 women did not continuo follow up. Of the 52 patients using Kaplan Meier survival curves we found actuarial continence at 3 months of 9.6%, at 6 months 27.7% and at 12 months 47.4%. When we analyzed the 34 patients that stayed incontinent versus the 18 that were continent at 1 year follow up we found that the presence of severe stress urinary incontinence (ISI>8) and parity were factors higher in the incontinent group, being parity the only variable with statistical significance (Parity: 4.4±2 vs., 3.0±3.0 p=0.019 and ISI> 8 58.8% vs., 33.3% p=0.08). Other variables did not reach statistical significance such as severity of the incontinence (p=0.08), age (p=0.75), BMI (p=0.19), presence of a cystocele (p=0.18), concomitant anterior culdoplasty (p=0.72), experience of the surgeon (p=0.58). There were no intra operating complications. Only found two exposed sling in the post operatory follow up which were solved on an outpatient setting and there was no surgery required for obstructive uropathy.

Conclusion:

Almost half of the patients that underwent a TOT procedure and were incontinent at 1 month follow up will stay incontinent after 1 year. Special interest should be given to those patients with high parity or a severe stress urinary incontinence preoperative. This analyzes raises the question of how long should we wait before suggesting the patient to go back to the operating theatre.

Presentation Number: 114

PERIURETHRAL INJECTION OF POLYACRYLAMID HYDROGEL AS A SALVAGE THERAPY FOR SEVERE STRESS URINARY INCONTINENCE IN WOMEN

J. CORNU, P. SÈBE, C. CIOFU, L. PEYRAT, O. CUSSENOT, F. HAAB;
Tenon Hosp., PARIS, France.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To assess clinical efficacy of a new bulking agent, polyacrylamid hydrogel (PAHG), for treatment of severe, complex cases of stress urinary incontinence (SUI) in women without urethral hypermobility after failed previous surgical management.

Background:

A prospective, observational evaluation was conducted from May 2008 to November 2010 in a tertiary reference center. Patients who presented with SUI after pelvic surgery or recurrence of SUI after surgical management were included. The following data were preoperatively collected: age, complete medical history, results of clinical examination with cough test, TVT and Bonney test, and preoperative urodynamics. All patients had SUI with a fixed urethra at clinical examination. 12 patients had associated OAB symptoms treated by anticholinergics. 36/50 patients had a maximal urethral closure pressure less than 30 cm H_20 (mean 25 cm H_20 ±12 [3–58]). No patient had pelvic organ prolapse. All patients had underwent prior surgical procedure involving urogynecological disease (table 1). Median number of previous pelvic procedures 3 [1–12].

Methods:

All surgical procedures were conducted under local anesthesia on an outpatient basis, by one very experienced surgeon. One milliliter of PAHG was injected in the urethral submucosa, one centimeter distal to the vesicourethral junction, under urethroscopy at 3, 6 and 9 o'clock. Patients were not catheterized and discharged 6 h later. A second procedure (re-injection) was conducted for patients unsatisfied of the results at the first evaluation at 1 month. Patient global impression of improvement (PGI-I) scale, pad usage, reports of SUI episodes on bladder diary and stress test at clinical examination were assessed at 1, 3, 6, 12 months and yearly thereafter. Patients were defined as cured for SUI when wearing no pads, having no stress-related leakage and presenting a PGI-I score of one or two, as improved in case of reduction of pad usage >50% and reduction of reported leakage episodes >50%, associated to satisfaction level of one, two or three. Otherwise patients were classified as failur. In case of re-injection, patients were followed according to the same protocol starting form the second procedure. Post-operative pain according to visual pain scale, bleeding, post-operative urinary retention, and any adverse event were recorded. Durability of the results was assessed by a Kaplan-Meier analysis about recurrence of pad use or SUI episodes during the follow-up period.

Results:

Operating time was 10 min and blood loss was minimal for all patients. All patients described their immediate post-operative pain as under 5/10 on visual pain scale. One patient developed a postoperative urinary retention that was managed by urinary catheter during 24 h. No patient was rehospitalized during the first post-operative month. 17 patients (34%) had two injection procedures. The median post-operative follow-up was 19±6 [10–30] months. At last follow-up, 17 patients (34%) were cured, 16 patients (32%) were improved, and 17 patients (34%) were not improved after the procedure. Survival without recurrence of pad usage is illustrated in Fig. 1. Pad usage was significantly reduced (p<0.0001). All presenting with OAB symptoms before surgery were still experiencing urgency during follow-up, managed by anticholinergics. Four patients experienced urinary tract infection during follow-up managed by antibiotics,

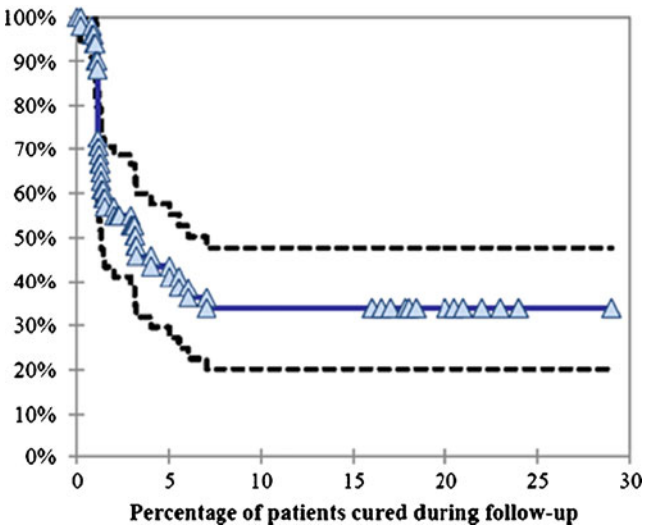
Conclusions:

With an overall success rate of 66%, PAHG is a safe and useful option in severe, multi-operated cases of women SUI with low

MUCP and a fixed urethra. These short term results have to be confirmed by larger studies.

Table 1 Selected literature data on performance of DFAFCs

Interventions	Number of patients concerned
Hysterectomy	12
Colposuspension	22
Mid urethral tape	30
Peri-urethral injections	9
Ajustable continence therapy (ACT)	4
Prolapse surgery	21
Artificial urinary sphincter	4
Urethro vaginal fistula	4
Cystectomy + neobladder	1
Stem cell therapy	1
Urethrolysis	3



Presentation Number: 115

LAPAROSCOPIC PARAVAGINAL REPAIR: OBJECTIVE OUTCOMES AT FIVE YEARS AND BEYOND

N. BEDFORD[1], E. SEMAN[1], R. O'SHEA[1], F. BEHNIA-WILLISON[1], J. COOK[1], M. KEIRSE[2];
[1]Flinders Med. Ctr., Adelaide, Australia, [2]Flinders Univ., Adelaide, Australia.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To present long term (5 years and beyond) data on laparoscopic paravaginal repair for anterior compartment prolapse.

Background:

The management of anterior compartment prolapse remains controversial. Traditional anterior colporraphy has performed poorly in recently published randomised controlled trials when used as the 'control' procedure. Alternatives include the use of synthetic mesh, allo- or xenografts, or paravaginal

Methods

Paravaginal repair as an alternative to anterior colporraphy has not been widely adopted. Vaginal, abdominal, and more recently, laparoscopic approaches are described. There is very little data in the literature concerning longer term outcomes of the laparoscopic approach.

Methods:

Data collection began in 1999 and continues prospectively for all patients requiring surgery for pelvic organ prolapse under the urogynaecology and endogynaecology units. Between 1999 and 2005, all patients with anterior compartment prolapse requesting surgical management were offered laparoscopic paravaginal repair with concomitant apical support unless there were contraindications to a minimal access approach.

POPQ was documented preoperatively and at subsequent visits. Patients were seen at 6 weeks, 6 months, and then annually or biennially thereafter. Data on symptoms of prolapse, urinary dysfunction and dyspareunia, as well as requirements for further management of recurrent prolapse were collected. For the purposes of this analysis, failure is defined in two ways (1)—development of prolapse in the treated compartment popq stage 2 or greater, and development of prolapse in the treated compartment at or beyond the hymenal remnant requiring further intervention.

Results:

The perioperative details, and short- and medium-term followup for this cohort have been previously reported (2,3). 279 women received laparoscopic paravaginal repair between January 1999 and December 2004. Data for 5 years or more is available for 95 women. Median followup time was 85 months (range 260–574, or 5–11 years). Ongoing efforts to review patients with incomplete followup will increase this dataset by June 2011.

At their most recent review, 69 women (73%) had objective success as defined as POPQ stage 0 or 1 in the anterior compartment. 44 women (46%) have no prolapse beyond the hymen, and have not required further surgery.

Overall 53 patients (56%) had an anterior failure (popq 2 or greater) at some time during the followup period and 34 of these women have had a further procedure. 17 women had an anterior colporraphy, 11 of which were augmented with full-thickness skin graft. 7 women had a porcine-graft reinforced repair, and 8 women had a permanent mesh repair, using a transobturator approach. 2 women are using pessaries for predominantly anterior recurrence. Median time to anterior failure was 36 months (range 6 weeks to 96 months). 12 women had failure within 12 months (13%). Denovo posterior compartment prolapse has occurred in 22 women (23%).

CONCLUSION:

Laparoscopic pelvic floor repair has the advantage of correcting support defects at the level of detachment. This has fundamental merit in prolapse surgery, as evidenced by the success of mesh sacrocolpopexy for vault prolapse. However the procedure is relatively time consuming and requires advanced laparoscopic suturing skills.

Our data show paravaginal repair is considerably more effective than traditional colporraphy at 12 months. With a median followup of 7 years, 46% of women evidenced cure without further surgery. Most women with anterior recurrence required only one further procedure, and most avoided permanent mesh. This makes the procedure particularly attractive where ongoing sexual activity is a priority.

As our understanding of prolapse continues to develop, laparoscopic paravaginal repair maintains a place in our management of anterior compartment defects. This data also represents an example of long term followup in prolapse surgery.

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Presentation Number: 116

PELVIC ORGAN PROLAPSE SURGERY WITH NON-ANCHORED MESH IMPLANTS AND VAGINAL SUPPORT DEVICE IN WOMEN WITH MODERATE SYMPTOMATIC PROLAPSE: PROSPECTIVE STUDY

L. KROFTA, M. KRCMAR, M. OTCENASEK, J. FEYEREISL, E. KASIKOVA, K. DLOUHA;
Inst. for the Care of Mother and Child, Prague 4, Czech Republic.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of this prospective study was to assess outcome of the system with non-anchored mesh technique to correct POP by the vaginal approach.

Background:

Surgical treatment of pelvic organ prolapse (POP) is associated with high recurrence rates. Around 17–29% of surgically managed patients require re-operation. There is incerasing evidence that the tension-free vaginal insertion of prosthetic mesh in patients with symptomatic POP reduces the chance of anatomic failure. A troacar-guided mesh systems are more suitable for POP stage III or IV according to the Pelvic Organ Prolapse Quantification (POP-Q) classification. Approximately 54% of symptomatic POP patients have moderate (POP-Q Stage II) prolapse.

Methods:

This is an open, prospective, observational study of patients operated with the Gynecare Prosima Pelvic Floor Repair System (Ethicon, Somerville, NJ) technique at one center between November 2009 and December 2010. A total of 49 women were included in the study (drop out 0 patients). Overall, 51% women had a prior hysterectomy and 64% had a previous POP surgery (1–5 previous POP surgeries). Women with symptomatic stage II prolapse by the POP-Q classification in anterior, posterior or both compartments were included in the study. Exclusion criteria were: 1) concomitant stress urinary incontinence procedure, 2) concomitant POP procedure, 3) previous POP mesh repair, 4) stage III or IV pelvic organ prolapse according to the POP-Q. In the group of women where the Prosima procedure was the primary surgery, severe morphological levator ani abnormalities where diagnosed (avulsion injury, hiatus area >25 cm ^{2}). Lower urinary tract symptoms before the procedure were present by 62% of women (13%-SUI, 27%-OAB, 22%-MUI). The pre-and postoperative evaluation (1 month, 3 months, 6 months and 1 year) comprised of a vaginal examination with the grading of the defect according to the POP-Q system of the ICS. Patients self-evaluated the severity of their POP symptoms with the use of a visual analog scale (VAS). Quality of life (QoL) assessment was performed using the QoL questionnaire: ICIQ-UI SF, PISQ 12, PFDI, PFIQ. The pre-and postoperative morphological evaluation was done with help of MRI and 3/4D ultrasound examination. Surgical procedures: the procedure was performed under general or regional anesthesia, antibiotic and venous thrombosis prophylaxis, digital rectal examination after posterior repairs and cystoscopy only in indicated cases. The mesh was inserted after hydrodissection and full thickness vaginal wall incision. The vaginal support device was removed after 28 days.

Results:

The mean age was 64.4±9.2 years (48–88), mean BMI 28.42±4.7 kg/m^2 (20.8–36.9), and mean parity was 2 (1–3). Mean follow-up 5.31 months (range 1–12). The surgical procedures were: Prosima Anterior - 20 (41%), Prosima Posterior - 19 (39%) and Prosima Combined - 9 (19%). Concurrent vaginal hysterectomy was performed in two patients. The mean operating time was 57.07 min. (range 20–120), and mean blood loss 59±89 ml (range 10–450). There were two (4.08%) major peroperative complications: one (2.04%) bladder perforation recognized during surgery (mesh was not inserted) and one (2.1%) severe bleeding episode (mesh was inserted). There were no other complications such as urethral, nerve or bowel injury. Early postoperative complications (day 0–7): a) febrile morbidity - 7.1%, b) VSD associated complications - 21.4%. There was no clinical hematoma or bleeding in the early postoperative period. Late postoperative complications (day 8–28): a) urinary tract infection - 12.8%, b) VSD associated complications - 42.0%, c) colpitis - 9.7%. The mesh exposure rate was 4.16%. The defect was localized in the anterior compartment. Mean time to exposure was 3 months. There was a significant decrease in the mean VAS score from 5.31±2.77 to 3.0 ±2.27. The incidence of micturition problems after the surgery reflex the significant positive change in ICIQ-UI SF values from mean 7.05±5.41 to mean 4.51±5.11. Stress

urinary incontinence by follow-up of 3 months was observed by 26% patients. Urgency by follow-up of 3 months was observed by 11% patients. We observed one (2.1%) case of POP recurrence after Prosima Combined insertion. In the anatomically cured group we found statistically significant changes in POP-Q points in treated compartment (Table 1).

Conclusions:

Our findings suggest that the interposition of a monofilament polypropylene non-anchored mesh and VSD is safe and leads to improved vaginal support at short term follow up in women with symptomatic POP Q stage II prolapse.

POP-Q	Anterior Prosima			Posterior Prosima		
Individual (cm)	baseline	6 m	stat.signif.	baseline	6 m	stat.signif.
Aa	−0.2	−1.1	s.s	−1.3	−1.7	n.s
Ba	0	−2.5	s.s	−2.2	−2.5	n.s
C	−2.7	−7.6	s.s	−2.7	−8.3	s.s
Ap	−1.3	−1.6	n.s	−0.4	−1.2	s.s
Bp	−2.3	−2.3	n.s	−0.7	−2.5	s.s
Gh	5.0	4.8	n.s	4.5	4.3	n.s
pb	4.0	4.3	n.s	3.7	3.8	n.s
TVL	6.4	7.8	s.s	6.3	8.0	s.s

Presentation Number: 117

VAGINAL HYSTERECTOMY AS A ROUTINE AMBULATORY SURGICAL PROCEDURE

M. GLAVIND-KRISTENSEN, S. GREISEN, U. T. LARSEN, S. FELSBY, C. POULSEN, S. M. AXELSEN, K. M. BEK;
Aarhus Univ. Hosp., Skejby, Aarhus N, Denmark.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To evaluate the redistribution of vaginal hysterectomies for uterine prolapse from a stationary unit to our Day Surgery Unit.

Background:

Traditionally, vaginal hysterectomy has been followed by hospitalization for several days but durong last decade the length of this hospitalization has been shortened to 24 h (1). Anterior vaginal wall repair has been shown to be suitable for an outpatient clinic (2) and this operation has been shown to be less costly in an outpatient regimen compared to an inpatient regimen without added risk of complications (3).

Methods:

This prospective, descriptive study comprised of 111 consecutive women admitted to a public Day Surgery Unit for vaginal hysterectomy in 2007–2010. Median age was 64 (37;87) years. One percent had grade 1 uterine prolapse, 59% had grade 2 uterine prolapse, 33% had grade 3 uterine prolapse, whereas 1% had grade 4 uterine prolapse. Concomitant prolapse operation was performed in 94% of the women. All women were operated under general anaesthesia induced by Remifentanil and Propofol supplemented by local anaesthesia in the cervix and the vaginal mucosa (Mepivacain 5 mg/ml with Adrenaline 5 μg/ml). The opening hours of The Day Surgery Unit were from 8 am until 5 pm.

Results:

Seventy-four women (67%) were discharged from The Day Surgery Unit after 253 (107;405) minutes in the recovery room. Of these women only three were seen in the stationary ward afterwards. This was due to urinary retention (N=2) and anxiety (N=1). Thirty-seven women (33%) were admitted to the stationary ward postoperatively due to pain (N=6), postoperative nausea and vomiting (N=6), indisposition (N=9), social reasons (N=8), urinary retention (N=4), surgery too close to closing of the unit (N=3), and intraabdominal bleeding (N=1). Three women (8%) were discharged on the night of surgery, whereas 32 (86%) on the day after surgery.

Conclusion:

Vaginal hysterectomy in the treatment of uterine prolapse is suitable for day surgery. However, admittance to a stationary ward should be possible. Alternatively, the opening hours of the Day Surgery Unit should be extended.

References:

1. Acta Obstet Gynecol Scand 2002;81:138–146.
2. Eur J Obstet Gynecol 2004;112:214–16.
3. Acta Obstet Gynecol 2007;86:473–79

Presentation Number: 118

TRENDS IN PELVIC ORGAN PROLAPSE SURGERY IN FINLAND IN 1987–2009

K. KURKIJÄRVI[1], R. AALTONEN[1], M. GISSLER[2], J. MÄKINEN[1];
[1]Turku Univ. Hosp. Dept. of obstetrics and gynecology, Turku, Finland, [2]Natl. Inst. for Hlth.and Welfare, Helsinki, Finland.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

The aim of the study was to evaluate the trends of surgical treatment of female pelvic organ prolapse (POP) in Finland from 1987 to 2009.

Background:

Surgery due to POP is common among women. A lifetime risk for prolapse or urinary incontinence surgery is estimated to be 11% by the age of 80. Quite recently prolapse operations have undergone a change as transvaginal meshes are becoming more popular. Their use and effect to the trend of the operative field is not yet known.

Methods:
The numbers of POP procedures were extracted from the inpatient care registry kept by National Institute for Health and Welfare (THL), which includes all Finnish women treated for POP. In 1987–1996 the procedures were coded according to the Finnish classification of surgical procedures and since 1997 based on the Nordic equivalent. Before the year 1997 there were 8 procedure codes for prolapse surgery whereas since then 14 codes have been used.
The operations were grouped into colpocleisis, operation for enterocele and colposacropexy before 1997 (procedures less than 270 per year) i.e. group Other in Table 1. Since 1997 the group Other also includes laparoscopic operation for enterocele and laparoscopic and/or vaginal repair of posthysterectomy apical prolapse. The number of mesh surgery can't be obtained from the registry because there is no specific code for it.

Results:
The total amount of POP procedures has increased 40% from 2290 in 1987 to 3240 in 2009. There was a sudden decline from 1996 to 1997 which is mainly due to a changed coding of separate vaginal hysterectomy when performed on non-prolapse indications. The rate of cervix amputation (Manchester operation) accompanied with colporraphies has seemingly diminished since 1990 (Fig. 1) while the rate of the group Other shows a steady increase until the last two years, probably owing to mesh use mostly being coded to this group. From 2005 to 2009 the total number of prolapse operations has decreased 20%.

Conclusion:
From 1987 to 2009 the total number of surgical procedures for pelvic organ prolapse has increased 40%, although a decline is seen in the last four years of this study. However, novel surgical methods such as transvaginal meshes show an increase in recent years.

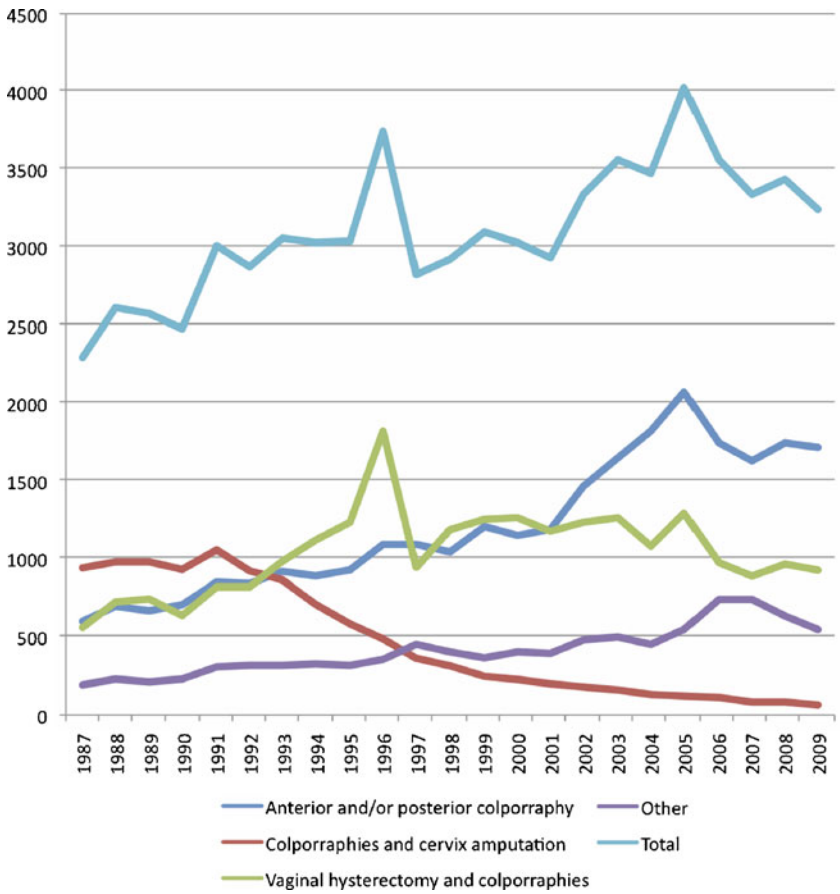

Figure 1 Procedures for pelvic organ prolapse in Finland in 1987-2009

Presentation Number: 119

COLOR DOPPLER URETERIC JET IN UROGENITAL PROLAPSE

T. LO, C. LIANG, A. WANG;
Chang Gung Mem. Hosp., Chang Gung Univ., Tao-Yuan, Taiwan.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
The aim of this study was to evaluate the color Doppler visualization of ureteric jets in the assessment of POP patients.

Background:
POP is associated with bladder outlet obstruction (BOO). Hydroureteronephrosis has been recognized in severe uterovaginal prolapse owing to long-term unrelieved BOO. When hydroureteronephrosis persists leading to irreversible renal dysfunction, chronic renal failure and end-stage renal failure may occur. There are no studies yet on Doppler ureteric jets in patients with POP and thus the role of ureteric jets in POP with bladder outlet obstruction and hydronephrosis remains unknown.

Methods:
Color Doppler US was performed on 40 severe POP (POPQ Stage II and IV) patients associated with voiding dysfunction and 20 controls. The hydroureteronephrosis was examined using B-mod US and IVP. Color Doppler US examinations were performed on patients when they felt the sense of urgency after being well hydrated. The number of peaks, maximum velocity (cm/s) and duration (s) of the jet were measured. Bladder outlet obstruction (BOO) was assessed using bladder outlet obstruction nomogram for women as suggested by Blaivas et al. Patients classified as no or mild BOO were grouped under "no BOO" while those classified as moderate or severe BOO were grouped under "BOO".

Results:
A total of 40 POP patients were recruited (22 were Stage III and 18 were Stage IV prolapse). The mean age was 66.3 years, median parity was 3, mean BMI was 26.3 kg/m^2. Among them, 28 had BOO and 4 had hydronephrosis. Urinary jets were identified and were satisfactorily recorded in all patients. The mean number of jets in 5 min was 11 (2.2/min). The number of jets seen in 5 min ranged from 5 to 17. The mean maximum velocity was 38.4 cm/s and mean duration of jet was 3.30 s. The comparison between 40 POP patients and 20 controls, the difference in mean ureteric jets frequencies, and mean maximum velocity of ureteric jets was not statistically significant. Yet, on the subgroups of BOO and hydronephrosis, ureteric jets of POP patients with BOO are of longer duration and lower velocity as compare to control group. Three types of waveform could be cataloged according to the nature of the peaks observed within that particular wave. Plateau type waveforms were much more common in POP patients associated with voiding and ureteric dysfunction than in normal.

Conclusions:
The results of our study indicate that longer duration and lower velocity of the ureter jet are strongly correlated with prolapse associated with bladder outlet obstruction. In POP patients, the presence of plateau-type waveform and decrease in frequency of ureteric jets on color Doppler US on POP patients indicate possible occurrence of hydronephrosis secondary to prolapse and ureteral dysfunction. As this is a small pilot study, we have planned further investigations to determine whether this test has demonstrated consistence results in assessing ureteric function in prolapse.

Presentation Number: 120

EFFECT OF TRANS-VAGINAL SURGERY ON LOWER URINARY SYMPTOMS AND MENTAL STATUS IN PATIENTS WITH PELVIC ORGAN PROLAPSE

M. KINJO[1], Y. YOSHIMURA[2], E. HIGASHIHARA[1];
[1]Kyorin Univ. Sch. of Med., Tokyo, Japan, [2]Yotsuya Med. Cube, Tokyo, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to evaluate the effect of trans-vaginal prolapse surgery on not only lower urinary tract symptoms (LUTS) but also mental status in patients with pelvic organ prolapse (POP).

Background:
It is well known that POP can co-exist with lower urinary tract symptoms, and greatly affect a women's quality of life (QOL), including social, physiological, occupational, domestic, and sexual life. But there are few reports about the relationship between POP and mental status. To determine the relationship between the POP and mental health, we analyze the changes of mental symptom before and after the surgery of POP patients.

Methods:
A total 89 POP patient who underwent trans-vaginal surgery were enrolled in this study. All patients were subjected to a

diagnostic work up of medical history, physical examination (containing transvaginal examination), the overactive bladder symptom score (OABSS, scoring the daytime urinary frequency, nighttime urinary frequency, urgency and urge urinary incontinence, validated in Japan), International Consultation of Incontinence Questionnaire of sort form (ICIQ-SF), and Hospital Anxiety and Depression Score (HADS, validated to detect anxiety and depression in a nonpsychiatric outpatient population. HADS Anxiety or Depression score 8 or more diagnosed as having clinical anxiety and depression). Questionnaires and examinations were completed before operation, at 6 month, and 12 month after the surgery. All participants provided oral informed consent before entering the study. For statistical analysis, paired t-test was used and p value <0.05 was considered statistically significant.

Results:

72 out of 89 (80.9%) patients were complete the examination and questionnaire. Mean age, mean body mass index, mean number of parity were 64.4±8.1 years, 23.2±2.4 kg/m^2, 2.4±0.8, respectively. Sixty-nine (95.8%) was postmenopausal. Baseline Pelvic Organ Prolapse Quantification (POPQ) stage distribution was; stage II; *n*=8 (11.1%), stage III; *n*=50 (69.4%), stage IV; *n*=14 (19.4%), respectively.

At the baseline, patients who were diagnosed as having clinical anxiety and depression status were 16 (22.2%) in anxiety, and 18 (25.0%) in depression.

At 6 month after surgery, ICIQ-SF total score, OABSS total score, and HADS Depression score were significantly reduced compared to preoperative scores (5.2±4.7 vs. 2.9±2.6, 3.2±2.4 vs. 2.2±1.6, 4.1±3.2 vs. 2.2±3.4,respectively) (p<0.05). But no significant difference was noted in HADS Anxiety score compared to preoperative score (4.2±3.7 vs. 2.9±4.5) (NS).

At 12 month after surgery, ICIQ-SF total score, OABSS total score, and HADS Depression score were significantly improved compared to preoperative scores (5.2±4.7 v.s.2.9±3.0, 3.2±2.4 v.s.1.9±1.5, 4.1±3.2 v.s.2.0±2.2, respectively). But also, there was no significant change in HADS Anxiety score compared to preoperative score (4.2±3.7 vs. 2.8±3.5) (NS). Although 9 patients (12.5%) remained as having clinical anxiety status, no one was diagnosed to having clinical depression status at 12 month after surgery.

Conclusions:

This study clearly demonstrated that trans-vaginal POP repair surgery was effective for not only LUTS but also patinents' mental health. However, it took 1 year to accomplish the relief of depression status, and anxiety status remained in some patients even at 12 month after surgery. It assumed that patients' fear for recurrence of prolapse affected the HADS Anxiety score.

At the best of our knowledge, this is the first report that shows of the relationship between trans-vaginal surgery and the mental status in Japanese female POP patients.

Presentation Number: 121

BIOMECHANICAL BEHAVIOR OF THE PELVIC FLOOR MUSCLES OF AN ELITE NULIPAROUS ATHELETE DURING VAGINAL DELIVERY

M. P. PARENTE[1], R. M. NATAL JORGE[1], A. A. FERNANDES[1], T. MASCARENHAS[2], M. P. ARAUJO[3];

[1]IDMEC - Pólo FEUP, Faculty of Engineering, Univ. of Porto, Porto, Portugal, [2]Faculty of Med., Univ. of Porto, Porto, Portugal, [3]UNIFESP, São Paulo, Brazil.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

Pelvic floor dysfunction is a hidden problem with a magnitude unknown to many. Statistics show that 1 in every 10 women will have pelvic floor dysfunction so severe that it will require surgery [1]. Several studies have shown that pelvic floor injuries during a vaginal delivery can be considered a significant factor in the development of urinary incontinence, fecal incontinence and pelvic organ prolapse.

The objective of the present work is to contribute to the clarification of the mechanisms behind pelvic floor disorders related to a vaginal delivery. For this purpose two numerical simulation based on the Finite Element Method were carried out. The Finite Element Model intends to represent the effects that the passage of a fetal head can induce on the muscles a specific pelvic floor, from a mechanical point of view. Two different thicknesses were considered for the muscles of the pelvic floor. According to data obtained by MRI, a thickness of 2 mm was used for a standard pelvic floor and, a thickness of 10 mm, to represent the pelvic floor muscles of a professional football player. The model used for the simulation represents the pelvic bones, with the attached pelvic floor muscles and the fetus.

Background:

The Finite Element Model used in this work was constructed using the geometrical point data obtained from cadaver measurements. All the measurements were performed on one embalmed 72 year old female cadaver obtained for scientific research. The specimen was selected for having no pathology to the pelvic floor. The cause of death was unknown and presumably not affecting the pelvic floor musculature [2].

Methods:

The simulation was performed using the implicit version of the commercial software ABAQUS. In this work the movements of the fetus during birth, in the vertex position were simulated. In

order to study the influence of the thickness of the pelvic floor muscles on the values of maximum stress obtained, the same simulation was repeated with the two different models for the pelvic floor.

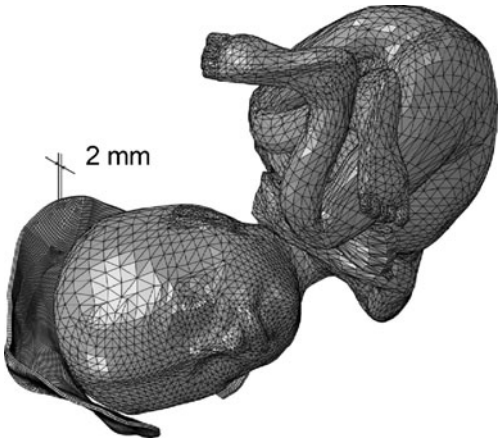

Figure 1: Fetus model and 2 mm pelvic floor.

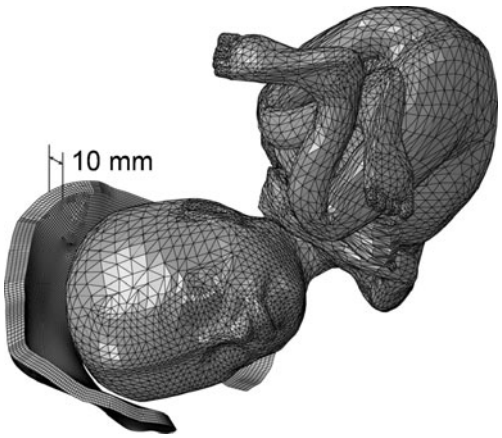

Figure 2: Fetus model and 10 mm pelvic floor.

Figure 1 shows the finite element model used for the fetus and standard pelvic floor. Fig. 2 shows the finite element model used to simulate a professional football player's pelvic floor.

The numerical simulations showed that when the pelvic floor thickness increased from 2 to 10 mm, maintaining unaltered the remaining dimensions of the vaginal canal, the values for the maximum principal stresses increased approximately 8%.

Conclusions:

The present work showed a non-invasive procedure that can be used in the future to estimate the damage that a vaginal delivery can induce on a specific pelvic floor.

References:

[1] - Obstet Gynecol (1997) 89; 501–506.

[2] - Int Urogynecol J (2007) 19; 65–71.

Presentation Number: 122

MANAGEMENT OF PREGNANCIES FOLLOWING THIRD AND FOURTH DEGREE PERINEAL TEARS: A MULTI DISCIPLINARY APPROACH

A. BONDILI, I. SIDDIQUI, W. NICHOLS, C. KETTLE, J. COOPER, F. O'MAHONY, K. ISMAIL, Pc - Mdt;

Univ. Hosp. of North Staffordshire, Stoke on trent, United Kingdom.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

To assess the impact of our perineal care multi disciplinary team (pc - mdt) care path way on post natal bowel symptoms in the women who had third and forth degree tear in previous pregnancies.

Background:

Currently there is sparse evidence in the medical literature in relation to the management of pregnancy following third and fourth degree perineal tears. In our unit all women who are pregnant with previous 3rd or 4th degree perineal tears are seen in a specific antenatal clinic. Women are asked about the presence or absence of bowel symptoms at booking and are offered an endo-anal ultrasound scan before 28 weeks of gestation irrespective of symptoms. Case histories and endo-anal scan findings are discussed in a monthly perineal care multidisciplinary team (pc-mdt) meeting where recommendations regarding mode of delivery are made. The mdt also provides advice on additional antenatal or postnatal investigations or referrals as deemed necessary such as manometry and biofeedback, particularly for women with significant bowel symptoms.

Methods:

This was a retrospective analysis of a perineal care multidisciplinary team database (pc- mdt) between January 2004 to December 2009 at an university affiliated hospital in united kingdom, a tertiary referral centre for perineal trauma. Case notes of 294 women were reviewed who delivered with a past history of a third or fourth degree perineal tears. Thirty four cases were excluded due to reasons such as either they did not have third/fourth degree tears in previous pregnancies or referred for mdt decision from different hospitals. So in total 260 notes were reviewed.

Results:

Out of 260 women 248 women had endo anal scanning. The results are shown in Table 1. In group A, 171 patients had minimal

external anal sphincter scarring (EAS) and intact internal anal sphincter (IAS) and were recommended to have vaginal delivery unless they got bowel symptoms. other three groups B, C, D (B+ C+D=77) who had either defect in IAS or scarring more than 2 h (as in clock) in EAS were recommended to have lower segment caesarean section (lscs). 132 women had vaginal delivery and 128 had LSCS. Increase in number of LSCS is due to other obstetric indications. at the start of the pregnancy 56 (21.5%) of 260 women were symptomatic. of which 18 (34%) women had faecal urgency, 15(27%) women had anal incontinence and 23 (39%) had mixture of symptoms (combined faecal and flatus symptoms). Women who were symptomatic were referred for anorectal physiology and/or rectal bio feed back. All women were offered and delivered by elective LSCS. At 6–8 weeks post natal follow up 33 women (12%) were symptomatic with the bowel symptoms. 39% improvement observed in faecal urgency, 40% improvement in faecal incontinence and 43% improvement in mixture of symptoms.Table 2. A previous audit conducted in our unit showed that the background risk of sustaining a 3rd or 4th degree tear was 1.5%. However, in this cohort of women who had vaginal delivery (n=132) the incidence of a recurrent 3rd or 4th degree tear was 7%.

Conclusion:

Our approach of multidisciplinary care in the management of pregnancies with a previous third and fourth degree tear appears to be effective in improving overall bowel symptoms which is statistically significant. There was a slight improvement in the individual bowel symptoms but it did not reach statistical significance. No patient developed de novo symptoms. Recurrent risk of third or fourth degree tear is increased by four fold.

Table 1 Endo anal scan findings total number n =248

less than 2 h eas scarring and intact ias (group a)	less than 2 h eas scarring and defect in ias (group b)	more than 2 h scarring in eas with intact ias (group c)	more than 2 h scarring in eas with defect in ias (group d)
171 (68%)	12 (5%)	36 (15%)	29 (12%)

Table 2 Improvement in the bowel symptoms - results

	antenatal n=260	post natal n=260	percentage of improvement	statistics p value*
faecal urgency	18	11	39%	0.18024
faecal incontinence	15	9	40%	0.2113
mixture of symptoms	23	13	43%	0.08364
symptomatic	56	33	43%	0.0012#

statistically significant

* z-test of proportions

References:

Int Urogynecol J (2009) 20:1095–1101

Eur Radiol (2006) 16: 1727–1736

Green top guideline no 29,RCOG; March 2007

Presentation Number: 123

OBSTETRIC ANAL SPHINCTER INJURIES AND ASSOCIATED RISK FACTORS

V. RAYO, M. SIMÓ, **O. PORTA**, I. GICH, J. CALAF;

Hosp. de la Santa Creu i Sant Pau, Barcelona, Spain.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

The main objective of this study was to analyze the risk factors associated with third- and fourth-degree obstetric perineal tears occurring during usual obstetric practice at our institution. Secondary objectives were to evaluate the incidence of obstetric anal sphincter injuries (OASIS), and the variation in incidence according to the type of delivery (spontaneous or instrumental) and type of instrument (vacuum extraction, forceps or Thierry's spatulas assisted vaginal delivery).

Background:

Incidence of OASIS varies widely in the literature but it is accepted to be amongst 0.5 and 5% of all vaginal deliveries. There seems to be a general agreement in the literature that forceps delivery increases the risk of OASIS when compared to spontaneous or vacuum-assisted delivery. However, little is known regarding Thierry's spatulas-assisted delivery.

The knowledge of obstetric risk factors in usual practice may lead to the implementation of preventive measures in the labour ward with the aim of enhancing women's health and wellbeing.

Methods:

In this observational prospective study of a cohort of patients, all deliveries that took place during the 1st January 2006 until 31st December 2009 were analyzed. Inclusion criteria were: all consecutive singleton, cephalic, vaginal deliveries. Cesarean sections, multiple pregnancies and non-cephalic presentations were excluded.

The main variable was the presence of a third- or fourth-degree tear according to Sultan's classification. Maternal variables studied were age, parity, anesthesia, spontaneous or induced onset of and duration of labor, and type of delivery. Neonatal variables were also considered: weight of newborn and blood cord pH values.

When considering the incidence of OASIS according to type of delivery, spontaneous delivery was taken as a reference and different instrumental types of delivery were matched and compared to it.

Episiotomy was not considered for evaluation as a complete description was not available in all medical records. When performed, the usual type at our institution is medio-lateral.

A descriptive analysis was made. The chi-square or Fisher's exact test were used when appropriate for categorical variables and the *t*-test was used for quantitative variables for the comparative analysis of the main variable with the rest of variables. A multivariant analysis was performed by means of a binary logistic regression model. Analyses were performed with the use of SPSS (V18.0) statistical package.

An anonymous database was created for the purposes of the study, which was reviewed and approved by the Ethics committee.

Results:

6130 deliveries were analyzed and 4526 fulfilled the inclusion criteria. A total of 97 OASIS were recorded. The overall incidence of OASIS during the 4-year period was 2.14% (CI 95%=1.72-2.57). For the results of the comparative bivariant analysis of maternal and neonatal variables and the presence or absence of OASIS see Tables 1 and 2. Results of multivariant analysis are shown in Table 3.

Table 1. Bivariant analysis of maternal and neonatal variables.

AGE (years)	31.33 with OASIS	31.02 non-OASIS	$p=0.54$
PARITY	2.9 nulliparous	1.3 multiparous	$*p<0.001$
SPONTANEOUS or INDUCED ONSET OF LABOR	2.0% OASIS in spontaneous	2.7% OASIS in induced	$p=0.287$
DURATION OF LABOUR (hours)	6.153 OASIS	6.155 non-OASIS	$p=0.995$
ANAESTHESIA	1.1% OASIS without anesthesia	2.4% OASIS with anesthesia	$p=0.026$
TYPE OF DELIVERY	1.1% OASIS if spontaneous	4.5% OASIS if forceps	$*p<0.001$
WEIGHT OF NEWBORN	3438.35 grs. OASIS	3263.89 grs. non OASIS	$*p<0.001$
BLOOD CORD pH	7.223 OASIS	7.234 non OASIS	$p=0.181$

Table 2. Bivariant analysis according to type of delivery.

TYPE OF DELIVERY	**OASIS**	**NON OASIS**	***TOTAL***
SPONTANEOUS	33 (1.1%)	3076 (98.9%)	*3109 (100%)*
VACUUM EXTRACTION	4 (2.7%)	145 (97.3%)	*149 (100%)*
FORCEPS	25 (4.5%)	528 (95.5%)	*553 (100%)*
THIERRY'S SPATULAS	35 (4.9%)	680 (95.1%)	*715 (100%)*
TOTAL	*97 (2.1%)*	*4429 (97.9%)*	*4526 (100%)*

Table 3. Multivariant analysis

VARIABLE	**COEFFICIENT**	**p**	**OR**	**IC 95% OR inferior**	**IC 95% OR superior**
WEIGHT	0,001	0,002	1,001	1,000	1,001
SPONTANEOUS		<0.001			
VACUUM EXTRACTION	0,920	0,087	**2,509**	0,876	7,189
FORCEPS	1,408	<0,001	**4,089**	2,406	6,949
THIERRY'S SPATULAS	1,569	<0,001	**4,804**	2,962	7,792

Conclusions:
The incidence of OASIS at our institution is within the ranges published in the literature (2.14%). Fetal weight and type of delivery are independently and significantly associated with OASIS. Fetal weight is a variable that cannot be changed. On the contrary, the type of delivery is chosen by the gynecologist and can be modified if necessary.
When compared to spontaneous delivery, vacuum extraction tends to increase the risk of an anal sphincter injury (OR=2.50, non-significant), forceps delivery increases 4-fold this risk (OR=4.08) while Thierry's Spatulas increases nearly 5-fold the risk of injury (OR=4.84).
Being aware of this information will definitely influence in the decision making in the labor ward and help the adoption of preventive measures to reduce the incidence of OASIS at our institution.

Presentation Number: 124

PELVIC FLOOR DYSFUNCTION AFTER LEVATOR TRAUMA 1 YEAR AFTER VAGINAL DELIVERY: A PROSPECTIVE CASE–CONTROL STUDY

L. SCHRUTKA, R. M. LATERZA, S. B. ALBRICH, G. NAUMANN, H. KOELBL;
Johannes Gutenberg Univ.-Mainz, Mainz, Germany.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of our prospective case–control study was to evaluate urinary, anal, prolapse and sexual symptoms in patients with levator ani muscle (LAM) trauma in comparison with patients with intact LAM 1-year after vaginal delivery.
Background:
It has been demonstrated that a LAM trauma and/or an enlargement of the urogenital hiatus influences the pelvic support and that women with levator defects may be around two times as likely to develop pelvic organ prolapse later in life. There is a lack of prospective studies considering if the LAM trauma could already be responsible of pelvic symptoms (meant as urinary, anal, prolapse and sexual symptoms) in the first period after delivery. This case–control study was intended to verify if the LAM trauma plays an independent role in the occurrence of postpartum pelvic floor disorders, investigating all aspects of pelvic functions.
Methods:
Primiparous women who delivered vaginally in our department between January-June 2009 and with 3D ultrasound diagnosis of LAM trauma on 2nd- 3rd day postpartum and confirmed one year later, were included in the case group of this prospective study. The control group was represented by primiparae women after vaginal delivery recruited in the same period with intact LAM in the early postpartum and 1-year 3D ultrasound assessment. Women presenting urinary, anal, prolapse and sexual symptoms or submitted to previous pelvic surgery prior to delivery or during pregnancy were excluded from our study.
LAM trauma was defined as a defect present in at least 3 consecutive tomographic slices at and above the plane of minimal hiatal dimension obtained with 3D perineal ultrasound (Fig.1) (1). All women were investigated on urinary, anal, prolapse and sexual symptoms with the validated German language of the Australian Pelvic Floor Questionnaire (2) 1-year postpartum.
Results:
Forty patients were included in our trial comprising 20 with and 20 without levator trauma. Patients', obstetrics' and fetal characteristics were comparable between the two groups, as shown in Tab.1 and Tab. 2.
Urinary symptoms were significantly increased in women with levator defect compared with controls (p=0.01). Anal and sexual symptoms worsened in the case group without reaching statistical significance (p=0.24, p=0.60, respectively). The two groups were comparable regarding prolapse symptoms (p=0.99). The Total Pelvic Floor Dysfunction Score was not statistically different between the two groups (p=0.214) (Tab.3).
Conclusion:
This is the first prospective case–control study evaluating pelvic floor dysfunction after levator trauma with a validated pelvic floor questionnaire in women 1-year after vaginal delivery. Except for urinary symptoms, our data suggest that levator trauma 1 year after vaginal delivery does not significantly affect pelvic floor function as soon as one year after delivery.
References:
1. Ultras Obstetr Gynecol 2009; 33:698–70
2. Int Urogynecol J 2009; 20:149–58.

Tab 1. Patients' characteristics

	Women with LAM defect (n=20)	Women without LAM defect (n=20)	Pv
Age (y)	30 (± 5.0)	31.5 (±4.8)	0.75
BMI	22 (18–32)	25.5 (16–44)	0.14
Caucasian, n (%)	20	17 (85%)	0.23
Sexually active	20	20	1

Tab.2 Obstetrics and fetal data

	Women with LAM defect (n=20)	Women without LAM defect (n=20)	Pv
Gestational age at delivery (d)	279 (247–290)	269 (183–292)	0.06
Fetal Weight (g)	3458 (±449)	3309(±481)	0.37
Fetal Circumference (cm)	35.45 (± 1.3)	34.68 (± 1.2)	0.06
Operative delivery (vacuum,forceps)	2 (10%)	2(10%)	1

Tab 3.Comparison of urinary, anal, prolapse and sexual symptoms between case and control groups.

	Women with LAM defect (n=20)	Women without LAM defect (n=20)	P
Urinary symptoms (score__/45)	3 (0–9)	1 (0–6)	*0.01*
Anal symptoms (score__/34)	2 (0–8)	2 (0–6)	0.24
Prolapse symptoms (score __/15)	0 (0–1)	0 (0–9)	0.99
Sexual symptoms (score __/21)	1.5 (0–6)	0 (0–9)	0.6
Total Pelvic Floor Dysfunction Score (score__/40)	2.4 (±2.0)	1.6 (±1.66)	0.21

Data expressed as median (range), mean ± SD or number (%).

Presentation Number: 125

EVALUATION OF OVERACTIVE BLADDER SYNDROME AND URGE URINARY INCONTINENCE SIX MONTHS AFTER FIRST DELIVERY

I. DIEZ-ITZA, M. ARRUE, L. IBAÑEZ, A. MURGIONDO, J. PAREDES, M. BELAR, C. SARASQUETA;
Hosp. Donostia, San Sebastian, Spain.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to evaluate the incidence of overactive bladder (OAB) syndrome and urge urinary incontinence (UUI) 6 months after first delivery and its effect on quality of life. We also investigated the factors involved in the development of OAB.

Background:
Overactive bladder syndrome with or without urge urinary incontinence is a common problem that affects millions of people worldwide. Its prevalence varies according to age and gender, among other factors. It is well documented that both OAB and UUI are more frequent in women and increase with age. Parity is another factor that has been associated with urgency (1) but there are only few studies focused on the evaluation of these symptoms short after delivery.

Methods:
This was a longitudinal cohort study including primigravid women who came to give birth at our Hospital from April to October, 2007. Exclusion criteria were: multiple pregnancy, gestational age of less than 37 weeks, diabetes mellitus, previous urogynecological surgery, urogynecological malformations and neurological disorders. We also excluded women who had urinary urgency before pregnancy.

An interview on urinary symptoms was held with pregnant women at term and 6 months after delivery, using the 2002 ICS definitions (2). The diagnosis of OAB and UUI was made when the woman answered 'yes' to the appropriate question, once we have ruled out any obvious pathology. All women were asked to complete the validated Spanish version of the Kings Health questionnaire (KHQ) at inclusion and on the 6 months follow-up visit. This condition-specific questionnaire allows evaluation of the effect of urinary symptoms on quality of life and has been validated for its use in overactive bladder patients (3). Pregnant women at term were prompted to answer the urinary questions and the KHQ questionnaire considering their symptoms before pregnancy.
To investigate the risk factors associated with OAB 6 months after delivery, we analyzed the following variables: maternal age; maternal body mass index; mode of delivery; use of epidural anaesthesia; augmentation of labour with oxytocin; length of second stage of labour; episiotomy; birth weight and newborn head circumference.
The statistical analyses used were T-test paired, Student's test and analysis of variance for mean comparison and Chi-square for percentages comparison.

Results:
During the study period, 462 pregnant women at term who came to give birth at our hospital were interviewed. Of those, 49 (10.6%) complained OAB prior to pregnancy and were consequently excluded. Of the remaining 413 eligible women, 357 (86.4%) attended the 6-month follow-up visit forming the study group. Their mean age was 31.4 years (range 18–46), and mean BMI was 23.3 (range 16.6–44.2). Of the total, 212 (59.4%) had a spontaneous vaginal delivery, 98 (27.5%) were delivered instrumentally and a cesarean section was performed in 47 (13.2%).
New development of urinary urgency after first pregnancy and delivery was detected in 39 (10.9%) women and UUI was

diagnosed in 25 (7%). The impact of urgency and UUI on quality of live was evaluated using the KHQ questionnaire. We first evaluated the changes from prior to pregnancy to 6 months postpartum in women who developed OAB and UUI. The mean score 6 months postpartum was significantly higher in women who developed OAB (11.38±10.74 vs. 5.09±5.79; p=0.004) or IUU (14.70±11.45 vs. 3.89±3.71; p=0.001). These results indicated deterioration of quality of life in both groups.

We also compared the mean score from women with symptoms six months after delivery and those from women without them. Women with overactive bladder or UUI had significantly higher scores (table 1) indicating worse quality of life.

The result of the multivariate analysis performed to associate OAB with different variables indicated that both prolonged pushing time (OR:3.28;95%CI:1.13–9.55) and instrumental delivery (OR:2.49;95%CI:1.16–5.35) were independently associated with OAB six months postpartum.

Table 1. Comparison of the KHQ questionnaire scores among the women with OAB or with UUI and those without symptoms

Urinary symptoms	**KHQ score** (Mean ± SD)	***P* value**
OAB		
No	4.02±4.49	0.000
Yes	11.39±10.59	
UUI		
No	4.11±4.61	0.000
Yes	12.88±11.73	

Conclusions:

The incidence of OAB 6 months after first delivery is 10.9% and of IUU is 7%. The women who developed OAB or IUU have deterioration of quality of life. These women have also a lower quality of live in comparison with the ones that are asymptomatic 6 months postpartum. Prolonged pushing time in second stage of labour is associated with a more than three-fold increase risk of suffering OAB 6 months after delivery whereas instrumental assisted vaginal delivery doubles the risk.

References:

1. Obstet Gynecol 2000; 96: 446–451
2. Neurourol Urodyn 2002; 21:167–78
3. Quality of life research 2003; 12:423–442

Presentation Number: 126

PELVIC ORGAN SUPPORT, SYMPTOMS AND QUALITY OF LIFE DURING PREGNANCY: A PROSPECTIVE STUDY

K. ELENSKAIA, A. H. SULTAN, R. THAKAR, I. SCHEER, J. L. ONWUDE;

Croydon Univ. Hosp., London, United Kingdom.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

To prospectively evaluate changes in pelvic organ support, pelvic floor symptoms and its effect on quality of life (QoL) during the first pregnancy using validated measures.

Background:

Good quality research regarding changes in pelvic organ prolapse (POP) during pregnancy is lacking. One prospective study reported a significant increment in POP stage using POP Quantification (POPQ) (1). However, the study was small and only 16 patients had repeat POPQ examination (2). Only one study reported on QoL but this was restricted to one domain (overactive bladder) (3).

Methods:

Nulliparous women over 18 years of age with a singleton uncomplicated pregnancy were invited at 20 weeks. Each domain of pelvic floor symptoms (urinary, bowel, vaginal, sexual), bother and QoL was evaluated using the paper version 3 of the validated electronic Personal Assessment Questionnaire (ePAQ-PF). This study was performed prior to the readily available electronic version. POP was assessed in the left lateral position using the validated POPQ system (1). POPQ and the questionnaire were repeated at 36 weeks gestation. Ethical approval (05/Q0806/9) and written informed consent was obtained.

Results:

182 nulliparous women at 20 weeks (mean age 29.7±5.5 years) completed the questionnaire and POPQ was performed in 175 women. 150 (82.4%) women attended the 36 week visit, 147 (80.8%) completed the questionnaire and 148 (81.3%) had POPQ performed. There was no significant changes in POPQ points or stage between the two visits except for a significant increase in genital hiatus (p< 0.05) and perineal body length (p<0.05) (Table 1). Table 2 shows the changes in urinary symptom domains. In the bowel symptom domains, significant improvement was seen in constipation (p= 0.02) and evacuation (p=0.009) subdomains, but not in the other subdomains such as irritable bowel symptoms (p=0.13), faecal continence/bother (p=0.15/0.69) and bowel related QoL (p=0.13). No statistically significant changes between two visits were found in the vaginal domain, including the following subdomains: vaginal sensation (p=0.21), bother from vaginal sensation (p=0.59), prolapse (p=0.18), bother with prolapse (p=0.99), vaginal symptoms and QoL (p=0.99). In the sexual domain only the changes in subdomain "sex and vaginal symptoms" were significant (p=0.03), but this was not bothersome (0.413). No changes were found in symptoms or bother of all the other subdomains of sex/urinary symptoms, sex/bowel symptoms, general sex life.

Conclusion:

Contrary to the findings of a previous small study (2), our prospective study revealed no changes in POPQ stage between the 2nd and 3nd trimester. However, symptoms and bother with voiding difficulties and stress urinary incontinence increased during pregnancy but did

not affect QoL. Despite popular belief to the contrary, we found that constipation and evacuation subdomains improve significantly during pregnancy and none of the pelvic floor symptoms impact on the QOL. These findings cast a very different perspective to previous assumptions and are therefore useful new information for pregnant women and their care givers.

References:

1. Am J Obstet Gynecol 1996;175:10–17
2. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:46–49
3. BJU Int 2006;97(2):296–300

Table 1.1 POPQ stage changes in antenatal period

Weeks	**20 [18–25] n 175**		**36 [31–39] n 148**	
POPQ stage	N%		N%	
0	84	48	63	43
1	76	43	80	54
2	15	9	5	3
Average POPQ stage	0.61		0.61	
Change from 20 weeks for matched pairs [p-value]			0.05 [0.44]	

Table 2: ePAQ-PF Urinary domains at 20 weeks and change at 36 weeks shown as a median score (range) and p value and where significant the bother is shown.

	20 weeks *N*=182	36 weeks *N*=147
Bladder pain	0 (0–41.7)	0 (0–33.3)
		0.23
		8.33 (0–41.7)
Voiding difficulty	0 (0–50)	0.003
Bother	0 (0–2)	0 (0–2)
		0.01
OAB*	8.3 (0–75)	8.3 (0–41.7)
		0.11
		6.67 (0–66.7)
SUI**	0 (0–40)	0.0001
Bother	0 (0–3)	0 (0–3)
		0.001
Urinary QoL	0 (0–100)	0 (0–88.9)
		0.07

*overactive bladder, ** stress urinary incontinence

Presentation Number: 127

Abstract withdrawn

Presentation Number: 128

RISK OF URINARY INCONTINENCE AFTER FIRST DELIVERY ASSOCIATED WITH PREGNANCY AND MODE OF DELIVERY−A 5-YEAR COHORT STUDY

C. LIANG, Y. LIN, L. TSENG, T. LO;
Chang Gung Mem. Hosp., Taoyuan, Taiwan.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To investigate the difference in the prevalence and risk factors of long term urinary incontinence 5 years after the first delivery between women who delivered vaginally and by cesarean section, and to compare the effect of urinary incontinence on the quality of life between these 2 groups.

Background:

In contrast to the abundance of cross-sectional studies, longitudinal studies addressing the natural history of urinary incontinence and examining the effects of delivery mode on urinary incontinence are rare.

Methods:

Between July 2005 and March 2006, primiparous women who delivered at our institute, a university hospital, after 36 gestation weeks were recruited to study the prevalence of the lower urinary tract symptoms (LUTS) before and during pregnancy. Exclusion criteria included toxemia, malignancy, psychological diseases, intractable DM, and severe cardio-pulmonary diseases. On the third through fifth postpartum day, each woman was asked to complete a structured urogynecological questionnaire with regard to LUTS, which met the definitions of the International Continence Society.

The same urogynecological questionnaire, the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) were mailed 5 years later. Non-responders were contacted twice by telephone. Responders were recruited for analysis and distributed into 2 groups, vaginal and cesarean deliveries. The impact of pelvic floor symptoms on 4 domains of life quality was measured: physical activity, travel, social activities and emotional health [1]. The Ethics Committee of our university hospital approved this study protocol.

In univariate analysis, the Chisquare test and the Fisher exact test were used to assess the significance of the associations for categorical variables and Students t test for continuous variables. Multivariate analysis was applied to calculate adjusted odds ratios for factors that showed significant associations in the univariate analysis. Data were analyzed using SPSS 17. P-values <0.05 were considered to be statistically significant.

Results:

There were no significant difference in demographic and reproductive characteristics between responders and non-responders. Two hundred seventy two responders were recruited for analysis. During pregnancy and at 5-year follow-up, the prevalence of stress urinary incontinence (SUI) increased from 26.7% to 50% and the prevalence of urgency urinary incontinence (UUI) grew from 4.7% to 22.1%. Our data also revealed that women who developed urinary incontinence in their first pregnancy had higher incidences of SUI and UUI at 5- year follow-up than those without pregnancy urinary incontinence (P=0.001 and P=0.033, respectively).

With respect to route of delivery, women who delivered vaginally had higher SUI and UUI than those delivered by cesarean section in primiparous women. Experiencing SUI 5 years after cesarean delivery had a significantly negative effect on emotional health (P=0.048).

Conclusions:
Urinary incontinence during the first pregnancy predicts an increased risk of having the symptom 5 years later. Women delivered by cesarean have a lower incidence of urinary incontinence at 5 years postpartum than through vaginal route. Later development of SUI inflicts more emotional stress on women receiving cesarean than those delivering vaginally.

References:
1. Uebersax JS et al. (1995) Short forms to assess life quality and symptom distress for urinary incontinence in women: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Nurourol Urodyn 14:131–9.

Presentation Number: 129

TRENDS IN OPERATIONS FOR FEMALE STRESS URINARY INCONTINENCE IN FINLAND IN 1987–2009

K. KURKIJÄRVI[1], R. AALTONEN[1], M. GISSLER[2], J. MÄKINEN[1];
[1]Turku Univ. Hosp. Dept. of obstetrics and gynecology, Turku, Finland, [2]Natl. Inst. for Hlth.and Welfare, Helsinki, Finland.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
The aim of the study was to evaluate the trends of surgical treatment of female stress urinary incontinence (SUI) in Finland from 1987 to 2009.

Background:
The dominance of Burch colposuspension in incontinence surgery has prevailed since the early 1980's in Finland. After the introduction of tension free tapes in 1998 the surgical treatment of female stress urinary incontinence (SUI) has gone through a drastic change. Different approaches (suprapubic, transobturator) with tapes have been developed and the total number of procedures seemed to be increasing.

Methods:
In Finland National Institute for Health and Welfare keeps an inpatient care registry. The numbers of different SUI procedures from 1987 to 2009 were obtained from the registry. The search was performed with procedure codes that up to 1996 were from the Finnish classification of surgical procedures and since 1997 are based on the Nordic equivalent system.

Results:
During the earlier classification, the most common procedure performed was Burch colposuspension while the others included vaginal operations, traditional sling procedures and prosthesis operations. All these in considerably smaller number compared with Burch colposuspension were therefore grouped into one ("others"). In the latter classification the number of procedures increased from 9 to 15 with significant alterations in coding. In order to show major changes we grouped the procedures as follows: laparoscopic Burch colposuspension together with open Burch procedure and all tension free vaginal tape procedures (suprapubic or transobturator) were grouped togerther in Fig. 1. However, in the Fig. 2 different transobturator tapes (TOT or TVT-O) as well as mini slings are grouped together. The rest of the procedures are minor in number and thus grouped as "other".
Before the introduction of tension free tapes Burch colposuspension was the most common procedure used in incontinence surgery in Finland. the number peaking in 1992. As tension free vaginal tape (TVT) came available in 1998 the number of procedures for SUI took a steep rise peaking in 2002. This resulted in a 2,5 fold increase in the total number of SUI procedures compared to the previous level. The transobturator techniques rapidly gained popularity since their introduction in 2003 and outnumbered TVT in 2007 (Fig. 2). By the year 2009 the total number of SUI operations has fallen by one third (Fig. 1).

Conclusions:
In Finland the tension free tapes have completely superseded Burch colposuspension and other former methods. The new non-invasive methods were also accompanied by a remarkable increase in the number of total operations. Recently the transobturator techniques are becoming the method of choice in SUI surgery in Finland.

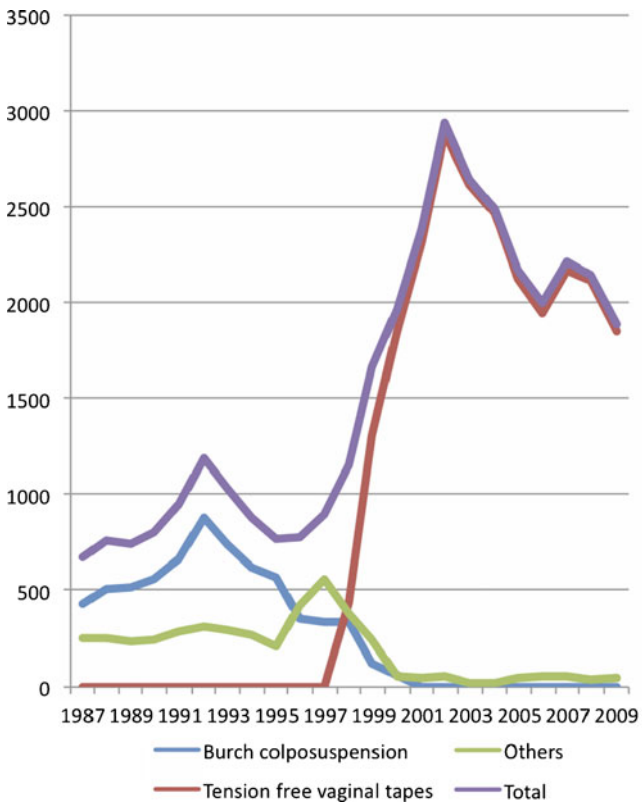

Figure 1. Procedures for stress urinary incontinence in Finland in 1987-2009

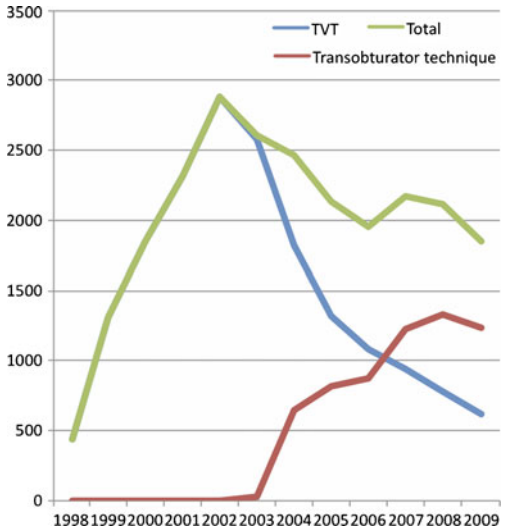

Figure 2. Tension free vaginal tape procedures in Finland in 1987-2009

Presentation Number: 130

VESICOVAGINAL FISTULA AFTER CESAREAN DELIVERY: THE ROLE OF PROLONGED LABOR VERSIS SURGICAL TECHNIQUE

T. CAPES[1], L. ROMANZI[2], E. STANFORD[3];
[1]Mt Sinai Med. Ctr., New York, NY, [2]Weill Cornell Med. Ctr., New York, NY, [3]Private Practice, Austin, CO.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective/Background:
In professional communications and multidisciplinary regional fistula conferences, there is a growing consensus of opinion that poor surgical technique causes the majority of genito-urinary fistula in women delivered abdominally. Given the paucity of data on this subject it was our aim to examine the relationship of cesarean delivery (CD) as a risk factor for obstetric fistula in women with genito-urinary fistula presenting to the General Referral Hospital of Panzi, Bukavu, Democratic Republic of Congo (DRC).

Methods:
This is a secondary analysis of 215 patients evaluated for obstetric fistula at the General Referral Hospital of Panzi, Bukavu, DRC from April to December 2009. Seventy-nine (79) patients developed genito-urinary fistula after cesarean delivery. A student t-test was used to compare CD and vaginal delivery (VD) groups.

Results:
Of the 215 women with fistula, 120 occurred after spontaneous or operative/assisted vaginal delivery (13 vacuum-assisted and 2 associated with symphysiotomy); 79 occurred subsequent to CD; 11 associated with gynecologic procedures; and none associated with sexual assault. In 5 patients the cause of their fistula was unknown. The mean age at presentation was 27.4 years (range 18–65). There was no difference in parity among CD and VD patients (CD 33 (41.7%) primiparous, 46 (58.2%) multiparous; VD 46 (38.7%) primiparous and 73 (61.3%) multiparous (p = NS).
All cesarean deliveries (100%) occurred in a hospital while 53 (55.9%) of VD were delivered in a hospital setting (p=<0.001). The stillbirth rate was high in both groups with fewer 63 (82.9%) occurring in the CD group compared to 109 (90.9%) in the VD group (p=<0.001). Overall, 50 (76.9%) who underwent a CD labored for greater than 2 days (23 (85%) primiparous and 27 (75.0%) multiparous). Similarly, a total of 88 women (39 (92.9%) primiparous and 49 (82.5%) multiparous) who delivered vaginally labored for 2 or more days. There was no statistically significant difference between CD and VD patients who developed fistulae and their length of labor (p=0.8).
Of the total 215 women, 7 fistulas involved the ureter and 12 involved the uterus. Five of the 7 ureteric fistulas were subsequent to CD, none were associated with vaginal delivery and 2 had no route of delivery data. Of those involving the ureter after cesarean delivery, 1 labored for greater than 2 days, 1 labored for 1 day or less and 3 had no length of labor reported. Eight of the 12 uterine fistulas occurred after CD, 4 after vaginal delivery. Of fistula involving the uterus after a CD, 5 labored for 2 or more days, 1 labored for 1 day or less and 2 had no length of labor reported.
Fifty-seven (73.1%) of the CD patients and 83 (73.5%) of VD patients underwent primary fistula repair at Panzi Hospital. Of the 215 women, 22 underwent abdominal fistula repair, 3 in the vaginal delivery group and 19 in the CD group.

Conclusions:
Much of the data about fistulae in developing countries comes from anecdotal reports or expert opinion. These data clearly show that the common mechanism of injury leading to obstetric fistula is obstructed labor for both vaginal and cesarean delivery. Concern that poor cesarean technique causes upper tract uterine and ureteric fistulae may be unfounded. These data show that for only 2 of the 79 abdominal deliveries was there a high index of suspicion that “poor surgical technique” may have been a cause. Any woman delivered by cesarean or vaginally whose labor lasts more than 2 days will suffer tissue necrosis and is at risk for fistula. Surgical technique may be implicated in only a small percentage of obstetric fistulae therefore, more timely access to operative delivery for prolonged labor is essential.

Presentation Number: 131

DO WOMEN SEEKING TREATMENT FOR PELVIC FLOOR DYSFUNCTION HAVE HIGHER THAN AVERAGE BMI'S?

B. L. ASTON, L. SHEEHAN, G. MAWU, C. ROBERTS, C. BARNICK;
Homerton Univ. Hosp., London, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this observational study was to assess the body mass index (BMI) of women with pelvic floor dysfunction (PFD) attending a clinic for conservative treatment and compare them to the UK national female obesity statistics.

Background:
As obesity levels in the UK increase, there is growing support for weight reduction programmes with government pledges to reverse the increasing trend for rising obesity. NICE obesity guidelines (2006) and Healthy Weight, Healthy Lives (2009) strategy which launched Change4life campaigns have led to increased access to obesity pathways. Obesity is associated and is the cause of many health complaints including pelvic floor dysfunction (PFD) (Wasserberg, 2009). Weight reduction has been shown to correlate with symptom reduction in women with PFD (Wasserberg 2009, Bump 1992).

Methods:
As part of the routine health assessment of women with PFD, the BMI was calculated for 161 women attending clinic. Ethical approval was not required, as BMI monitoring is considered standard practice in the trust.

Results:
BMI's ranged from 18 to 65.3. The mean BMI was 29.2, higher than the national average of 26.9. In addition, 75.3% of clinic attendees were overweight or obese. This was higher than the national average of 56.9%.

Figure 1: National female BMI results compared to local clinic results

BMI	2008 *	Results (n=166)
Underweight/under 18.5)	2.0%	1.8%
Normal/18.5 to less than 25	41.1%	22.9%
Overweight/25 to less than 30	32.0%	39.2%
Obese/30 to less than 40	24.9%	29.5%
Morbidly Obese/>40	2.8%	6.6%
Overweight, including obese	56.9%	75.3%
Mean BMI	**26.9**	**29.2**

*Health Survey for England - 2008 Trend Tables. The NHS Information Centre, 2009. Available at: http://www.ic.nhs.uk/pubs/hse08trends

Conclusions:
These observational results demonstrate that women seeking treatment for PFD have higher than average BMI's. As health care professionals we should be identifying obesity in this high risk group of women and using local pathways to help weight reduction, as an integral part of PFD management.

References:
Bump RC, Sugarman HJ, Fantl A and McClish DK (1992). Obesity and lower urinary tract function on women: Effect of surgically induced weight loss. American Journal of Obstetrics and Gynecology, 167:392–399.
Wasserberg N, Petrone P, Haney M, Crookes PF and Kaufman HS (2009). Effect of surgically induced weight loss on pelvic floor disorders in morbidly obese women. Annals of Surgery, 249(1):72–6.

Presentation Number: 132

DELIVERY MODE IN NULLIPAROUS WOMEN AND POSTPARTUM URINARY INCONTINENCE: A NATIONAL MULTI-CENTER PROSPECTIVE COHORT STUDY IN MAINLAND CHINA

L. ZHU[1], J. LANG[1], L. LI[1], S. HAN[2];
[1]Peking Union Med. Coll. Hosp., Dept. of O/G, Beijing, China, [2]Peking Union Med. Coll., Dept of epidemiology, Beijing, China.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To obtain epidemiological data on the delivery mode in nulliparous women and its impact on the development of UI in mainland China.

Background:
Our previous epidemiological study revealed that the national prevalence of urinary incontinence(UI) was 30.9%. That cross-sectional survey, 20,000 Chinese women aged≥20 years were randomly selected and interviewed with modified Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaires to estimate population prevalence rates and identify potential risk factors. Vaginal delivery was the major risk factor for stress urinary incontinence(SUI). Objective of this research is to obtain epidemiological data on the delivery mode in nulliparous women and its impact on the development of UI in mainland China.

Methods:
The study was conducted to follow up 10418 nulliparous women since their early pregnancy from Sep 2007 to May 2009 in 14 maternity units in seven regions. Modified Bristol Female Lower Urinary Tract Symptoms (IQ-BFLUTS) questionnaire was used to collected data on delivery mode in nulliparous women and to estimate prevalence rate of UI at 6 months postpartum.

Results:
A full dataset was available for analysis in 10098 women. Delivery mode in Chinese nulliparous women was vaginal

delivery 51% versus cesarean section(C-section) 49%. C-section rate was significantly higher in urban nulliparous women(54.9%) than in rural women(43%)($P<0.001$). Elective C-section rate was 27.5%, while 21.5% for emergency C-section. Elective C-section rate was significantly higher than emergency C-section rate both in urban and rural nulliparous women ($P<0.001$).

Prevalence of UI at 6 months postpartum was 10.1%(522/5154)for vaginal delivery versus 3.3%(165/4944)for C-section($P<0.001$). No significant difference of postpartum UI prevalence rate was seen between elective C-section group and emergency C-section group in 6-month follow-up ($P=0.719$).

Multivariate Logistic Regression Analysis of delivery mode revealed that C-section was protective factor for SUI of nulliparous women at 6 months postpartum. No significant difference of postpartum SUI prevalence rate was seen between elective C-section group and emergency C-section group in 6-month follow-up.

Conclusions:

C-section rate was nearly 50% in Chinese nulliparous women, which was higher in urban women than rural ones. Short term labor cause no risk of injury to pelvic floor. C-section is the protective factor for postpartum UI.

Presentation Number: 133

BUCCAL MUCOSA GRAFT URETHROPLASTY FOR FEMALE URETHRAL STRICTURES

M. CERVIGNI[1], E. PALMINTERI[2], E. BERDONDINI[3], F. NATALE[4], M. PANEI[1], A. MAKO[1];

[1]S. Carlo-IDI Hosp., Rome, Italy, [2]Ctr. fo Urethral Reconstructive Surgery, Arezzo, Italy, [3]Ctr. for Urethral Reconstructive Surgery, Arezzo, Italy, [4]S.Carlo-IDI Hosp., Rome, Italy.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Background:

Urethral strictures in women have long been debated with regard to their etiology and impact on voiding patterns. Multiple etiologic factors are suspected: iatrogenic, radiation inducing urethral fibrosis, prolonged urethral catheterization or surgical repair. Often repeated urethral dilation with subsequent fibrosis due to bleeding and extravasation are among the most frequent causes of iatrogenic urethral strictures. Surgical treatment in these cases is still debated. It varies from a simple vaginal flap to pedicle labial skin tube urethroplasty wrapped with labial fat or omentum depending on stricture complexity.

Buccal Mucosa graft (BMG) represents the gold standard for urethral reconstruction in males with complex urethral strictures. In male strictures graft urethroplasty using a dorsal approach to the urethra has shown improved urethral reconstruction. This Video shows the technique of urethral stricture correction in females using BMG for urethroplasty with a dorsal approach according to the technique described by Migliari et al.

Methods:

With the patient under general anesthesia in the dorsal lithotomy position, the head is placed in the right position to harvest the BMG from the right inner cheek. A buccal retractor is inserted to prepare the field and to protect the tongue. Three stitches are placed at the level of the rima oris to expose the cheek mucosa, then the Stenone duct is identified to avoid a possible inclusion during harvesting of the graft. A lozenge 5–6 cm long and 2 to 3 cm wide is prepared after a saline and vasoconstrictor injection.The Buccal Mucosa Graft is harvested. Interrupted 3-zero absorbable sutures are used to close the denuded mucosa. Then the defacting of the sub mucosa is carried out. A Nelaton catheter 6 to 8 French is iserted into the urethral lumen to identifie the distance of stricture from urethral meatus and marked by a dermographic pen. The dorsal part of the urethra is exposed by a reversed U-shape incision over the meatus starting from 3 to 9 o'clock position. The vulvar mucosa is separated from the urethral channel and a plane is developed between the underlying urethra and overlying clitoral cavernous tissue. The incision is made through the entire thickness of the dorsal urethra (mucosa and spongiosal tissue). During dissection the anterior portion of the striated urethral sphincter is identified and moved upward or if necessary cutted if the stricture interests the middle/proximal third of the urethra. A 3-zero stitch is placed on the dorsal surface of the urethra as close as possible to the apex of the incision. Buccal mucosa graft tailored is sutured to the right margin of the urethral plate and then to the left margin with 3-zero interrupted stitches with knots outside lumen. Left side of buccal mucosa graft is sutured to epithelial margin of opened urethra in the same manner. Distally the Buccal Mucosa Graft is tailored and split to achieve a normal meatal slit-like appearance. The margins of augmented dorsal urethra walls are re-aproximated and quilted to the clitoris body to cover the new urethral roof. Finally, the vestibular area and vulvar mucosa are closed with 2-zero interrupted Vycril sutures. Patients were discharged home after 2 days. After 15 days the catheter was removed. A post-void residual urine is checked to evaluate restarting of normal micturition.

Conclusion:

in our experience this technique is safe, easy to perform but may be tested in larger series and long-term follow-up to evaluate if it could be offered as a primary or subsequent procedure in the treatment of the stenosis of the distal urethral.

References:

R. Migliari, P. Leone, E. Berdondini, M. De Angelis, G. Barbagli: Dorsal buccal mucosa graft urethroplasty for female urethral strictures. J Urol 176: 1473–76, 2006

Presentation Number: 134

BIOLOGIC GRAFTED REPAIR OF URETHROVAGINAL FISTULA AND CONCOMITANT SYNTHETIC SLING

A. L. SMITH, G. W. DAVILA;
Cleveland Clinic Florida, Weston, FL.

BIOLOGIC GRAFTED REPAIR OF URETHROVAGINAL FISTULA AND CONCOMITANT SYNTHETIC SLING

Smith AL, Davila GW

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

This video presents a surgical technique in which interposition of a biologic graft between a urethrovaginal fistula repair and tension-free synthetic sling can enhance success without significantly increasing patient morbidity.

Background:

Urethrovaginal fistulas are rare but can occur following obstetrical trauma and surgical procedures including urethral diverticulectomy, anterior colporrhaphy, and incontinence procedures. A patient may or may not complain of incontinence depending on the size and location of the fistula. However, it has been estimated that approximately 50% of women will develop symptoms of incontinence following repair[1,2] and debate over the appropriate management of concomitant stress incontinence currently exists.

Methods:

Our patient is a 66 yo who presented with complaints of stress incontinence and continuous urine loss since a diverticulectomy 10 years prior. On examination with methylene blue instilled into the bladder, a 0.3 cm fistula in the distal urethra was seen. Office cystoscopy confirmed the opening of the fistula tract to be in the distal urethra and urodynamic testing confirmed the presence of concomitant stress urinary incontinence.

We begin the fistula repair by confirming its location with placement of a lacrimal duct probe into the tract. During the dissection, wide mobilization of the periurethral tissue laterally is necessary to ensure a tension-free closure. We perform a modified Latzko technique in which the fistula tract is not extensively excised if viable tissue is present and is oversewn with the periurethral tissue. Due to the patient's symptomatic stress incontinence placement of a transobturator sling is necessary. Prior to sling placement, a biologic interposition graft is used to cover the repair, protecting the suture line and providing support. This is analogous to the usage of a labial fat pad/Martias graft but with less associated morbidity. We use bovine pericardium, a non-crosslinked biologic graft consisting of multi-directional collagen fibers that provide an excellent matrix for host tissue ingrowth. At completion of the surgery, a vaginal packing is placed for 24 h and a foley catheter for 10–14 days.

Results:

At 2 weeks after surgery our patient had a negative voiding cystourethrogram and transurethral drainage was discontinued. Postoperatively, she continues to be followed in our clinic without any evidence of fistula recurrence, stress incontinence, mesh exposure or healing complications. To date, 7 patients at our institution have undergone fistula repair with concomitant synthetic sling and interposition of a biologic graft. Retropubic slings were placed in 4 patients and transobturator slings in 3 patients. Mean age was 57±11.7, BMI 29.2±7.2, and parity 2 (1–3). At a median follow-up of 88 weeks (12–342) there have been no healing complications, and all report themselves as "cured" or "greatly improved" without any complaint of stress incontinence.

Conclusions:

The utilization of a biologic graft interposition allows for a successful fistula repair and concomitant synthetic sling without an increase in complications.

References:

1. Int Urogynecol J 2007; 18:343–346.
2. Int Urogynecol J 2010; IUGA/ICS abstract # 393.

Presentation Number: 135

MODIFIED COLPOCLEISIS

K. RAMALINGAM, L. STOCKER, A. MONGA;
Princess Anne Hosp., Southampton, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

The purpose of this study was to evaluate the efficacy and effects on, prolapse, bowel and bladder symptoms of colpocleisis and partial vaginectomy

Background:

With advancing age expectancy, vault prolapse is increasing in incidence. Various surgical procedures are available as definitive treatment such as sacrospinous fixation, open or laparoscopic sacrocolpopexy or Le Fort's Colpocleisis. However, in elderly or frail patients and in those with comorbid medical disorders who are at a high risk of anaesthetic complications, this new modified surgical technique may be a better option. It is considered in such patients who are not sexually active. It may be performed under a regional anaesthetic and benefits from shorter surgical time and quicker recovery after surgery.

The technique involves infiltration of the vaginal wall with 20mls of 1% Lignocaine and 1:100,000 adrenaline. A longitudinal incision is made over the entire length of the vagina from inferior

to the urethra upto the posterior vaginal wall. The endopelvic fascia is dissected off the overlying vaginal wall throughout the incision. The endopelvic fascia is approximated in the midline to render a layer of support. The excess vaginal wall is excised as much as possible without creating tension along the closure of the incision.

Methods:

Prospective, evaluation study of 14 patients who underwent this procedure in a tertiary hospital in the UK. The follow-up ranged from 6 to 20 months. Audit approval obtained.

Results:

All 14 patients stayed in the hospital overnight and were discharged the next day. No intraoperative or immediate post-operative problems occurred.

13 out of 14 patients felt that the prolapse symptoms had improved and 1 patient did not find any difference from before. Out of 8 patients who reported pre-operative bladder symptoms, 5 patients noted an improvement in symptoms, 1 patient needed suprapubic catheter for ongoing urinary incontinence and 2 patients noted worsening of urinary frequency. Of the 2 patients who reported pre-operative bowel symptoms, both reported improvement in their obstructive defaectory problems. None of the 14 patients were sexually active before or after the procedure. No residual vaginal wall prolapse was noted in any of the 14 patients.

Conclusions:

This new modification is a safe procedure for the treatment of vault prolapse. Significant improvement occurred in quality of life, prolapse, bowel and bladder symptoms. Large numbers and longer term follow-up is required to further evaluate.

References:

1. A preliminary report on pelvic floor reconstruction through colpocleisis from 2001 to 2007 at the University Hospital of the Puerto Rico Medical Center

2. Surgical treatment for pelvic floor disorders in women 75 years or older: a single-center experience

3. Obliterative procedures for pelvic organ prolapse

Presentation Number: 136

REPAIR OF THE MESH INDUCED VESICOVAGINAL FISTULA USING MARTIUS FLAP AND FIBRIN GLUE AFTER PRIMARY UNSUCCESSFUL FISTULA CLOSURE

I. M. IGNJATOVIC[1], D. STOSIC[2], N. MEDOJEVIC[1], M. POTIC[1];

[1]Clinical Ctr. Nis, Urology, Serbia, [2]Clinical Ctr. Nis, Gynecology, Serbia.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Introduction: Correction of pelvic organ prolapse (POP), and stress urinary incontinence is mainly performed using different forms of synthetic materials-meshes. They are frequently used due to simplicity of the surgery, as well as, durable results regarding correction of both incontinence and prolapse. Complications are rare and frequently simple. However it is not always the case. The most troublesome complication of the mesh surgery is late migration of the mesh in the bladder (urethra) and formation of the vesicovaginal fistula. It commonly occurs after time interval, long enough for mesh adhesions formation.

Method:

Forty seven years old female patient had "Prolift anterior" surgery, in January 2010, because of POP. Fistula was formed 2 months after the surgery. In the meantime minor symptoms were present. Removal of the mesh was subsequently done and, vesicovaginal fistula closure according to Martius flap technique. Surgery failed and fistula was reopened. Three months later, after the secondary surgery, Martius flap fistula closure was performed on the other side, with the additional use of fibrin glue. Two months after the surgery she is dry and continent, with the POPQ grade II.

Results:

Martius flap together with fibrin glue was performed in 11 cases for vesicovaginal fistula closure. All of them appeared after gynecological/obstetrical incident. Treatment was successful after the first surgery in 10 patients, and described patient was the most demanding due to success after secondary surgery of the fistula, mesh adhesions, and position close to the bladder neck. Although the main principles like: infection prevention, tension free suture, anatomical preparation, and tissue interposition, are essential for the success of surgery, fibrin glue can be considered as an additional tool to obtain a watertight closure of the fistula.

Conclusion:

It must be kept in mind that mesh surgery is performed for the improvement in quality of life. Complications of mesh surgery are sometimes very difficult.

Presentation Number: 137

A SURGICAL CASE INVOLVING BLADDER ENDOMETRIOSIS

C. CHENG, M. HEALEY;

Royal Women's Hosp., Parkville, Victoria, Australia.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

This video presentation shows a surgical case of severe endometriosis involving a bladder endometriotic nodule. Surgery involves a combined laparoscopic and transurethral approach to excise the nodule together with partial cystectomy of the bladder.

Endometriosis involving the urinary tract is rare and only occurs in approximately 1% of all patients with endometriosis (1).

Surgery often involves a multidisciplinary approach with gynaecological laparoscopic surgeon and urologist. The surgery itself is technically difficult as the nodule is densely adherent to both bladder and uterus.

This presentation of the surgery demonstrates an example of such case.

Reference

1. Int J Urol 2006;13:902–4

Presentation Number: 138

LABHARDT'S COLPOPERINEOCLEISIS: THE REVIVAL OF AN ANTIQUE TECHNIQUE?

J. A. PIZARRO BERDICHEVSKY, G. GALLEGUILLOS, R. CUEVAS, M. ARAMAYO, S. GONZALEZ, M. FERNANDEZ, J. KUSANOVIC, V. MIRANDA, A. MAJERSON, J. ORTIZ, M. SANHUEZA;

Hosp. Dr. Sótero del Río/División de Obstetricia y Ginecología Facultad de Med., Pontificia Univ. Católica de Chile, Santiago, Chile.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:

To present our experience with the use of Labhardt's Colpoperineocleisis (LC), a minimally invasive surgery for correction of pelvic organ prolapse (POP).

Background:

Surgical correction of POP has the goal to correct urinary and/or fecal incontinence, as well as to restore vaginal anatomy and function. The latter may be of less importance in patients without sexual activity. Last year we reported on IUGA a smaller cohort with a shorter follow-up (abstract # 700).

Methods:

Retrospective cohort study including patients with POP and without sexual activity who underwent LC between January 2008 and April 2010. The main affected compartment, POP severity and hysterectomy history was not relevant to decide the surgical treatment. Clinical charts were reviewed to collect information including demographic characteristics, symptoms, gynaecological exam (including POPQ quantification), as well as follow-up at 3 weeks, 6 weeks, 3 months, 6 months, 1 year, and then yearly. Recurrence was defined as stage II or higher according to POPQ. Patients were asked for surgery satisfaction and subjective change in quality of life (QoL) 3 months after surgery and then in every visit. All patients provided written informed consent before surgery.

Surgical technique: Posterior mucosal rhomboideal incision with the vertices at 1 cm below the posterior cervical lip and 2 cm above the anus. Resection of lateral vaginal mucosa started from the union of the two upper thirds of the posterior incision until the mucocutaneous junction, 2 cm below the urethral meatus. Vaginal mucosa is closed starting at the nearest vertex to the cervix using #000 Vycril continuous sutures. Midline high plication of the puborrectalis part of the levator ani muscles and the bulbospongiosus, with #0 PDS separated suture. Superficial plane of #1 Vicryl suture to cover the PDS knots is placed. Skin is closed with #000 Vicryl.

Results:

64 LC were performed in the study period. Demographic characteristics are shown in Table 1 (all Tables values are expressed as number (percentage) or mean ± SD or median (interquartile range)). In preoperative POPQ classification, one patient was in stage I, 3 stage II, 41 stage III and 19 stage IV. 94% of patients were stage III and IV. The most affected compartment was the anterior in 43 patients (67.1%), the apical in 18 (28.1%) and the posterior in 3 (4.7%). Average POPQ are shown in Table 2. Perioperative data are displayed in Table 3. Follow-up details are shown in Table 4. 9 patients (14%) were managed with oral antibiotics (ciprofloxacin and metronidazole) at some point within the first month after surgery. All of them had genital discharge, in 5 cases this was a foul smell but without local signs of inflammation. One patient developed fever 12 days after surgery and was managed as an outpatient with antibiotics and analgesia. No patient required hospitalization for complications associated with surgery.

Conclusions:

LC is an excellent alternative for elderly patients without sexual activity, improving QoL and associated with high patient's satisfaction. It is fast, with a very low blood loss, no intraoperative complications, and few or minimal post-operative complications. The rate of recurrence needing surgery was very low (6,1%). To our knowledge, this is the biggest cohort of Labhardt's colpoperineocleisis reported so far since last 40 years. Further prospective studies with a larger sample size are needed to confirm these results.

Median age (years)	72 (67–75,5)
Mean total parity	4,4±2,8
Mean vaginal spontaneous birth	4±3
Median heaviest newborn weight (grams)	3695±687
Median menopause age (years)	45,7±5,88
Mean BMI (kg/m^2)	27,3±4,5
Previous gynaecological surgeries	
POP (no details)	3
Vaginal Hysterectomy with or without anterior or posterior colporrhaphy	3
Anterior colporrhaphy + TOT	1
Non POP abdominal hysterectomy	2

Compartment (n)	Aa	Ba	C	gH	pB	TVL	Ap	Bp	D
General (64)	2 (0–3)	4 (0–3)	1±4,4	5±1,3	3 (2–3)	8 (7–9)	−1 (−2-0)	-1 (−2-1,75)	−3,4±2,6
Anterior (43)	1,4±1,6	3,5±1,7	−0,5±3,7	4,8±1,2	3,1±0,8	7,9±1	−1,3±1,5	−1,1±1,9	−3,9±2,5
Apical (18)	2±1,5	4,3±2,2	5,6±1,8	5,6±1,2	2,9±0,9	8,4±1,3	0,5±2,2	1,6±3,3	−1,6±1,5
Posterior (3)	−2±1,5	−2,3±1,1	−4,3±1,5	6,7±1,1	2,3±0,6	7±1,7	2,7±1,1	3,7±0,6	−7±1,4

Median operating time (min)	45 (40–60)
Median estimated blood loss (ml)	50 (30–100)
Intraoperative complications	1[1]
Concomitant vaginal surgeries	8[2]
Median post surgery hospital stay (days)	2 (2–2)

[1] Doubtful transrectal sutures were removed to be repositioned, no changes in hospitalization, infection or recurrence. [2] 2 TOT, 4 VH, 1 dorsal lipoma extration, 1 D&C.

Mean follow-u (month)		11,6±5,3
Less than 6 month		6 (9,3)
Surgical satisfaction	Yes	57 (89)
	No	2[1] (3,1)
	Unresponsive	5 (7,8)
After surgery QoL	Better	57 (89)
	Equal	2[1] (3,1)
	Worse	0
	Unresponsive	5 (7,8)
General recurrence		8 (12,5)
	Symptomatic	8 (12,5)
	Asymptomatic	0
	Requiring surgery	7[2] (10,9)
Median follow-up at recurrence (month)		2,5 (1,5-4)
De novo SUI		3 (4,7)

[1] Both were symptomatic recurrence [2] All recolpoperineocleisis with optimal results in 7,3 month of average follow-up.

Presentation Number: 139

MESENCHYMAL STEM CELLS FACILITATE RECOVERY AFTER SIMULATED CHILDBIRTH INJURY VIA SECRETED FACTORS

C. DISSARANAN, M. A. CRUZ, **B. M. COURI**, R. JUAREZ MENDIETA, B. M. BALOG, L. SALCEDO, B. GILL, M. KIEDROWSKI, M. S. PENN, H. B. GOLDMAN, M. S. DAMASER;
Cleveland Clinic, Cleveland, OH.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Stem cells have recently gained attention as a potential therapy for stress urinary incontinence (SUI) [1]. Recent studies have suggested that stem cells facilitate repair by secretion of paracrine-acting proteins such as growth factors [2]. This study investigates if intravenously (IV) delivered bone marrow-derived mesenchymal stem cells (MSCs) home to the urethra and facilitate functional recovery after simulated childbirth injury and to determine if this recovery is due to factors secreted by the MSCs.

Background:
Vaginal delivery is a major risk factor for development of SUI. During vaginal delivery nerves, pelvic floor muscles, and connective tissues responsible for maintaining continence have been shown to be compressed and injured. Although sling procedures are highly effective for SUI, there is no present therapy to facilitate repair after childbirth injuries or prevent occurrence of these disorders. We have previously demonstrated that monocyte chemoattractic protein-3, a stem cell homing cytokine, and its receptors are upregulated in the urethra and vagina of rat after childbirth injury [3], suggesting that MSCs delivered systemically after delivery will home to these organs and facilitate repair. Media that has been concentrated and conditioned by MSCs (CCM) is widely used to assess if secreted proteins form the basis of the mechanism by which these cells facilitate repair. Determination of the pacracrine factors that facilitate repair after injury would provide insight into potential therapeutic agents to encourage tissue repair after childbirth injury and prevent SUI.

Methods:
Age-matched virgin female Sprague–Dawley rats were divided into 8 groups; 6 were used in the functional arm of the study: vaginal distension (VD) and IV saline (N=6), VD and IV MSCs (N=7), sham VD and IV saline (N=5), VD and intraurethral injection of CCM (N=5), VD and intraurethral injection of concentrated control media (N=4) and sham VD & intraurethral injection of concentrated control media injection (N=5). Two groups were used in the imaging arm of the study: VD and IV MSCs (N=4), sham VD and IV MSCs (N=4). For VD, a modified

10Fr Foley catheter was inserted into the vagina and inflated balloon to 3 ml for 4 h. One hour after injury, 2 million GFP-labeled MSCs or saline was injected via tail vein. CCM or control media was concentrated 50 times and injected directly into the exposed urethra. Outcomes were tested 1 week later by simultaneous leak point pressure (LPP) and external urethral sphincter (EUS) electromyography (EMG). Bladder pressure was recorded in a filled bladder via urethral catheter while EUS EMG was recorded both at rest and while the bladder was gently compressed to induce leakage. LPP as well as mean frequency & amplitude of 1 s segments of EUS EMG both at baseline and during LPP were statistically compared using a Kruskal-Wallis One Way ANOVA on Ranks, followed by the Dunn's posthoc test. To assess homing, the urinary bladder, urethra, vagina and rectum were harvested from each animal in the imaging arm 7 days after VD or sham VD and imaged ex vivo for visualization of GFP positive cells using a supercooled charge coupled device camera in a light tight box. Total fluorescent flux (photons/s/cm^2/steridian) from each organ was statistically compared between VD and sham VD groups using a t-test. $P<0.05$ was taken to indicate a statistically significant difference between groups.

Results:

LPP was significantly reduced in VD rats treated with saline or control media compared to sham VD but not in those given IV MSCs or CCM, suggesting that both MSCs and CCM provided a therapeutic effect after simulated childbirth injury. In contrast, amplitude and frequency of the EUS EMG both at rest and during LPP testing in rats with VD treated with MSCs or CCM was significantly decreased compared to rats with sham VD. Ex vivo imaging showed significantly higher flux in the vagina 7 days after VD than 7 days after sham VD, indicating that more MSCs homed to the vagina after VD than after sham VD. Flux in the urethra, bladder, and rectum was not significantly different between rats that underwent VD and sham VD, suggesting that stem cells preferentially homed to the vagina after VD.

Conclusions:

MSCs delivered IV home to the urethra and facilitate recovery after childbirth injury but not by increasing EUS function. Intraurethral injection of CCM appeared to act in a similar manner, suggesting that improved LPP may result from the local secretion of paracrine factors by MSCs. Mechanisms underlying the observed therapeutic effects of MSCs and CCM and development of potential therapeutic agents to prevent development of pelvic floor disorders merits further investigation.

References:

[1] Current Urology Report (2011) 12:41–46
[2] Journal of Vascular Transplant Research 3 (2010): 547–485
[3] Journal of urology (2008) 180:753–759

financial support from the State of Ohio

Presentation Number: 140

VAGINAL FIBROBLASTS OF WOMEN WITH PELVIC ORGAN PROLAPSE SHOW A DIFFERENT RESPONSE TO CYCLIC MECHANICAL LOADING DEPENDING ON THE POP-Q STAGE AND SURFACE SUBSTRATE

A. RUIZ ZAPATA[1], **M. H. KERKHOF**[2], B. ZANDIEH DOULABI[1], H. A. BROLMANN[1], M. N. HELDER[1];
[1]VU Univ. Med. Ctr., Amsterdam, Netherlands, [2]Kennemer Gasthuis Hosp., Haarlem, Netherlands.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objective:

The aim of this study is to determine whether POP fibroblasts display altered functional characteristics depending on the severity of the disease.

Background:

Although surgical techniques for correction of pelvic organ prolapse (POP) have undergone many modifications, reoperation rate for persistent or recurrent prolapse remains unacceptably high. New therapies such as cell-based tissue engineering, may provide promising alternatives by creating effective pelvic and vaginal support through tissue repair and regeneration. Although risk factors for POP are well known, the exact cause still needs to be elucidated.

To gain insight in the underlying mechanisms of POP, this study aimed to identify whether POP fibroblasts display altered functional characteristics depending on the severity of the disease. This was assessed by subjecting fibroblasts from mild and severe POP patients to cyclic mechanical loading under different coating conditions, and subsequent analysis of morphology and catabolic compounds affecting extracellular matrix quality.

Methods:

Retrieval of biopsies from female POP patients was approved by the medical ethical committees of both hospitals, and informed consent was obtained. Isolated vaginal fibroblasts were cultured for 3–5 passages, then seeded at a density of 150,000 cells/well on 6-well uncoated or collagen I-coated bioflex® plates and subjected to either static (unloaded) or cyclic mechanical loading (Flexercell; 0,2 Hz) conditions for up to 48 h. Morphology and intra- and extracellular matrix metalloproteinases (MMP) enzyme levels were determined.

Results:

Morphology assessment showed induction of alignment upon stretching perpendicular to the force. Alignment was most apparent in fibroblasts from mild POP patients (Fig. 1a,b vs. Fig. 1c,d). Collagen type I coating facilitated attachment and subsequent alignment (Fig.1a and 1c). Zymogram analysis of cell lysates and conditioned culture media, after 24 h in uncoated plates, revealed the presence of both inactive (pro

MMP-2) and active MMP-2 in fibroblasts from severe POP patients (SPOP), but virtually only inactive MMP-2 in fibroblasts from mild POP patients (MPOP). Under static conditions, both inactive and active MMP-2 were increased in SPOP vs. MPOP. At 24 h in collagen-coated plates, the level of pro MMP-2 was higher in MPOP than in SPOP. Mechanical loading inhibited pro MMP-2 production by SPOP. All samples were devoid of MMP-9 (data not shown). After 48 h, three forms of MMPs were identified in the conditioned media: inactive MMP-2, active MMP-2 and inactive MMP-9. In uncoated plates active MMP-2 showed increased activity when cells were stretched. This effect was more pronounced in MPOP (Fig.1f). In collagen-coated plates, the presence of MMPs seems similar between samples regardless the type of donor or kind of stimulation (Fig.1e).

Conclusions:

Vaginal fibroblasts from both sets of patients with prolapse showed similar morphological changes in response to cyclic mechanical loading. Matrix degradation by MMPs from vaginal fibroblasts in response to mechanical stress appears time- and substrate-dependent. The general tendency that fibroblasts from severe POP patients display earlier upregulation and higher levels of MMP-2 suggest that those fibroblasts are more prone to matrix degrading activities compared to fibroblasts from mild POP patients, in particular when their collagenous surroundings are compromised.

We conclude that the POP fibroblasts display differential responses depending on the severity of the disease. This should be taken into account when developing new tissue engineering-based concepts for treatment of pelvic organ prolapse.

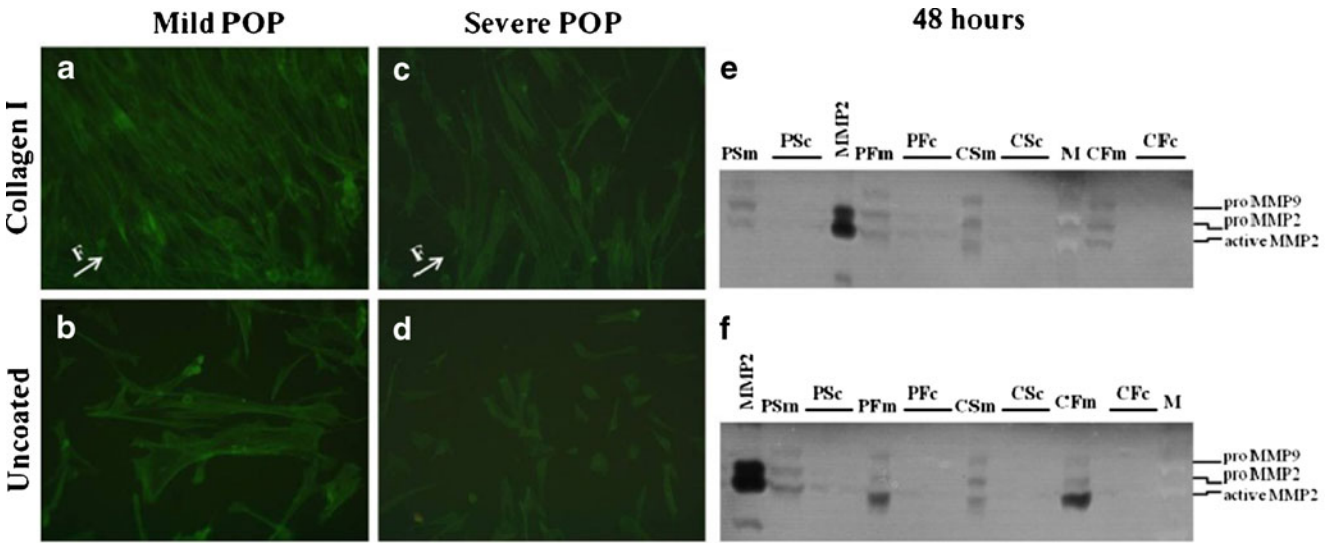

Fig. 1 Morphological and enzymatic changes under different loading and coating conditions. Cells were seeded on 6-well bioflex® plates coated with Collagen type I(a, c and e) or uncoated (b, d and f) and subjected or not to cyclic mechanical loading. **(a)**, **(b)**, **(c)** and **(d)** are representatives images of actin fibers from vaginal fibroblasts under cyclic mechanical loading for 24 hours. Note that Collagen I facilitated cell attachment and subsequent cell alignment (a and c) perpendicular to the force (F). Fibroblasts from mild POP (a) showed more alignment than fibroblasts from severe POP (b) patients. [F-Actin fibers stained with phalloidin, images magnification 10x]. **(e)** and **(f)** are zymograms from conditioned media and cell lysates after 48 hours. Results were analyzed for matrix metalloproteinase 2 (MMP2) and metalloproteinase 9 (MMP9). [F cyclic mechanical loading by Flexercell; S static; P severe POP fibroblasts; C: mild POP fibroblasts; c: cell lysates; M: molecular weight marker; MMP2: human recombinant matrix metalloproteinase-2].

Presentation Number: 141

A SIMPLIFIED METHOD OF BIOMARKER NORMALISATION FOR URINARY CONCENTRATION

R. CARTWRIGHT
G. VIJAYA, V. KHULLAR;
Inst. of Reproductive and Dev.al Biology, Imperial Coll. London, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To validate a novel simplified method of normalising urinary biomarker levels against urine concentration.

Background:
In the search for a reliable, non-invasive alternative to urodynamics, much interest has focused on urinary biomarkers, with their potential for immediate bedside testing. As urine concentration shows wide intra- and inter-patient variability, assessment of any biomarker derived from the urothelium requires normalisation for a measure of urinary concentration. Currently available assays for potential overactive bladder (OAB) biomarkers, including prostaglandin E2 and urinary Nerve Growth Factor (NGF), recommend normalisation against urinary creatinine levels. This study aimed to demonstrate that urine photometric absorbance measured at 450nM wavelength, can serve as an alternative to measurement of urinary creatinine, and assess the validity of the method using the recognised association between urinary NGF and OAB severity.
Methods:
Following ethical approval and written informed consent, urine samples were collected from adult women presenting with lower urinary tract symptoms. Urine samples were aliquotted, with one aliquot saved for measurement of urinary creatinine, and one aliquot spun to extract sediment, with the supernatant then frozen at −80°C for storage, before processing using the NGF Emax ImmunoAssay System (Promega, Madison, WI, USA). Following the plating of urine samples onto 96 well microtitre plates, absorbance was measured at 450nM using an OptiMax microplate reader (Molecular Devices, Sunnyvale, CA, USA). Spearman's correlation, and automated curve fitting were used to assess the association of urine absorbance and urinary creatinine concentration. Receiver operator statistics were used to compare the efficacy of conventional creatinine normalisation and absorbance normalisation when using NGF as an OAB biomarker.
Results:
120 women provided urine samples. Median urine creatinine was 6630microM/L (792–22497 5th-95th centiles). Urine creatinine was strongly correlated with absorbance (rho=0.806, $p<.0001$), with the optimal curve fitting model being a power model (r2= 0.552). Although there was a trend towards higher NGF levels in women with OAB, receiver operator curves for urinary NGF as a predictor of OAB demonstrated poor prognostic value for creatinine normalisation (AUC 0.47), with a marginally improved performance with absorbance normalisation (AUC 0.56).
Conclusions:
Urinary NGF is non-specifically raised in association with a variety of functional lower urinary tract conditions. In a typical clinical population, assessed using formal test statistics, urinary NGF has minimal prognostic value. Although NGF is not an effective biomarker for OAB, normalisation for urine concentration can be simply achieved using spectrophotometry, rather than separate measurement of urinary creatinine levels. This technique could reduce the cost and complexity of ELISAs and other absorbance detection assays for a range of urinary proteins, and may simplify the discovery, validation and implementation of future potential biomarkers.

Presentation Number: 142

A PHASE 2 STUDY EVALUATING THE SAFETY AND EFFICACY OF TWO DOSES OF A MONTHLY OXYBUTYNIN VAGINAL RING IN WOMEN WITH SYMPTOMS OF OVERACTIVE BLADDER

M. GITTELMAN[1], **K. Z. REAPE**[2], S. DASEN[2], H. I. HAIT[3]; [1]South Florida Med. Res., Adventura, FL, [2]Teva Women's Hlth. R&D, Horsham, PA, [3]Edenridge Associates, Wilmington, DE.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:
To evaluate the safety and efficacy of two doses of oxybutynin vaginal ring (VR), administered once monthly, compared to placebo, in women with overactive bladder (OAB) who have symptoms of predominant or pure urge incontinence, urinary urgency, and urinary frequency.
Background:
Non-oral modes of delivery of oxybutynin result in a reduction in the production of the active metabolite (N-desethyloxybutynin), which is associated with the presence of classic anticholinergic side effects. Such a reduction would be expected to be observed with vaginal administration as well. The monthly oxybutynin vaginal ring was designed to provide effective, convenient long-term delivery; the safety and tolerability of two doses were assessed in this Phase 2 study.
Methods:
In this multicenter, randomized, double-blind, placebo-controlled study, 719 women with symptoms of overactive bladder were enrolled at 68 sites in the US and Canada and randomized to one of three treatment groups (placebo, 4 mg/day oxy VR and 6 mg/day oxy VR). All subjects started with a three-week placebo run-in phase. Upon successful completion of the run-in, defined as demonstration of ≥10 urge incontinence episodes per week, average urinary frequency of ≥8 voids/24 h and average total void volume of ≤3.0 L/24 h, 445 total subjects entered the 3-arm, 12 -week treatment phase (155 received placebo VR, 143 received oxy 4 mg/day VR, 147 oxy 6 mg/day VR). Rings were changed once a month. OAB voiding diaries were collected for 3 days at baseline (end of the 3-week placebo run-in period) and prior to visits at weeks 4, 8, and 12. The primary measure of efficacy was the change from baseline to Week 12 (end of treatment [EOT]) in the total weekly number of incontinence episodes. Secondary efficacy measures included the change from baseline to Week 12/EOT in average daily urinary frequency, average void volume, average severity of urgency and proportion of subjects with no incontinence episodes recorded in the final diary. Safety was assessed by summarizing adverse events reported throughout the study.
Results:
Efficacy: Both active treatment groups demonstrated greater reductions compared to placebo in the total weekly number of

incontinence episodes. The primary efficacy analysis cohort was the intent-to-treat (ITT), defined as those randomized, treated patients who had baseline data and at least one post-baseline data point for the primary efficacy endpoint. The modified ITT (MITT) consisted of those ITT subjects who met all three efficacy inclusion criteria at baseline that defined OAB (≥10 pure or predominant urge incontinence episodes per week, average urinary frequency of ≥8 voids/24 h and average total void volume of ≤3.0 L/24 h).

Table 1. Change from Baseline to End-of-Treatment in Total Weekly Number of Incontinence Episodes

	Tx	N	Baseline	Mean Change ± SD	P-value (vs. placebo)
MITT	**Pbo**	**112**	**28.25**	**−13.77 ±14.50**	
	4 mg	**115**	**28.34**	**−16.76 ±16.45**	**0.036**
	6 mg	**96**	**26.52**	**−16.70 ±14.30**	**0.018**
ITT	**Pbo**	**133**	**26.44**	**−13.16 ±14.65**	
	4 mg	**132**	**26.34**	**−15.38 ±16.12**	**0.061**
	6 mg	**119**	**25.12**	**−15.18 ±16.24**	**0.185**

Average daily urinary frequency was reduced by 0.60 voids/24 h in the 4 mg/day group (p=0.072) and 0.93 in the 6 mg/day group (p=0.0004) for the ITT cohort, compared to reductions of 0.70 (4 mg/day, p=0.104) and 1.0 (6 mg/day, p=0.002) for the MITT. No significant differences between either of the active groups and placebo for either cohort were observed for the change in average void volume.

Safety: The overall incidence of AEs was greatest in the oxy 6 mg/day group, with a dose-dependent incidence of dry mouth (2.6% in the placebo group, 4.9% in the 4 mg/day group, 10.2% in the 6 mg/day group) and urinary tract infection (4.5% in placebo, 9.1% in the 4 mg/day group, 12.2% in the 6 mg/day group) being observed. Other AEs that occurred with an incidence rate of ≥2% in any group included sinusitis, respiratory tract infection, nausea, yeast infection, abdominal pain, diarrhea, constipation, vaginal discharge, vaginal pain, vaginal bleeding, vaginal erythema, dysuria, backpain, increased hepatic enzymes, and headache; all with an incidence of <5%. There were a total of 8 subjects (1.8%) who experienced a serious AE during treatment (4 in the 6 mg/day group and 2 each in the 4 mg/day and placebo groups), although none were related to study medication.

Conclusions:

Both the 4 mg/day and 6 mg/day doses of the oxybutynin monthly vaginal ring appeared to be well-tolerated and exhibited similar levels of demonstrated efficacy compared to placebo for the primary efficacy endpoint of reduction in the weekly number of reported incontinence episodes.

Presentation Number: 143

PROSPECTIVE, RANDOMIZED CLINICAL TRIAL OF A NOVEL, NONINVASIVE, PATIENT-MANAGED NEUROMODULATION SYSTEM (PMNS) USING A SACRAL PATCH FOR THE TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER

A. B. MONGA[1], R. DMOCHOWSKI[2], D. MILLER[3], D. ALTMAN[4]; [1]Southampton Univ. Hosp. Trust, Hampshire, United Kingdom, [2]Vanderbilt Univ. Med. Ctr., Nashville, TN, [3]Wheaton Franciscan Hlth.care, Glendale, WI, [4]Danderyd Hosp., Stockholm, Sweden.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:

To evaluate the efficacy and safety of a noninvasive sacral PMNS patch for the treatment of patients who suffer from symptoms of overactive bladder (OAB).

Background:

Most physicians and scientists support the theory that faulty communication between the central nervous system and the bladder plays a role in OAB (1), but treatment remains problematic. Anti-muscarinic drugs are the mainstay of therapy, but their associated side effects lead to poor compliance and reduced usefulness (2). As an alternative, stimulation of sacral nerves through transcutaneous or

implanted electrodes has been shown to relieve the clinical symptoms of OAB without additional drug, surgical, or behavioral intervention (3). This 4-week clinical trial assessed the safety and efficacy of a novel, noninvasive PMNS, administered via a self-contained patch, in patients who had previously failed other therapies, including at least one anti-cholinergic drug, for OAB.

Methods:

This multi-center, prospective, randomized clinical trial was performed in male and female subjects at least 18 years of age with documented symptoms of OAB for a minimum of 6 months. Additional eligibility criteria included failure of conservative OAB therapies such as behavior modification and failure of at least one anti-cholinergic drug prescribed for OAB. Subjects underwent a 7-day washout from anti-cholinergic medications, if applicable. Three days prior to the study, subjects completed a 3-day voiding diary to serve as a baseline and help confirm eligibility. A mean of eight or more voids and one urgency urinary incontinence episode per 24-h day was required for enrollment.

The PMNS transmits a transdermal amplitude-modulated signal (TAMS), composed of a carrier signal and pulse envelope, through a patch applied to the skin with the aid of a placement tool. It is controlled by a wireless handheld remote control. All subjects underwent treatment with the PMNS patch for a total of 4 weeks (Weeks 1–4). Subjects were randomized to one of two treatment groups in which the PMNS patch was positioned either by the investigator (Investigator Placement Group, IPG) or the subject (Subject Placement Group, SPG) in a precise location of the sacral region using the placement tool. The investigator placed the patch and adjusted the amplitude for all subjects at the outset, regardless of placement group. Subjects in the IPG returned every 7 days for patch removal and placement of a new patch on the contra-lateral side. All subjects were trained in operation of the PMNS. Subjects in the SPG returned on Day 7 for investigator observation of patch self-placement and replaced their patch at home for the remaining 2 weeks. A second, 3-day voiding diary was completed by all subjects during the last 3 days of Week 4. Adverse events were collected throughout the study. Statistical analysis was performed using the Wilcoxon signed-rank (intra-group) and Wilcoxon rank-sum (inter-group) tests.

Results:

A total of 74 eligible subjects were enrolled, with a final $N=30$ in the IPG and $N=34$ in the SPG. Of note, no significant inter-group (SPG vs. IPG) differences were observed for any of the four endpoints at baseline or Week 4 ($P>0.4$), indicating that SPG and IPG groups were comparable at baseline, and that patch placement appeared to be equally effective regardless of whether it was performed by a subject or the investigator. As a result, the SPG and IPG data were combined and analyzed for overall treatment outcomes (Table 1).

*Table 1 OAB patient outcomes after 4 weeks of PMNS treatment**

	Baseline**	Week 4	Change from baseline%	Change from baseline	*P* value
Primary Endpoint					
Urgency incontinence episodes	4.9 (3.2)	2.2 (2.5)	−2.7 (3.1)	−47.8 (60.6)	<.0001
Secondary Endpoints					
Voiding frequency	11.3 (3.1)	9.4 (2.7)	−1.9 (2.5)	−15.0 (19.1)	<.0001
Volume per void	179.4 (66.7)	187.6 (75.0)	8.2 (46.7)	7.5 (26.4)	0.0371
Urgency episodes	10.0 (3.6)	7.8 (3.3)	−2.2 (2.8)	−21.2 (28.6)	<.0001

* combined total of IPG and SPG, $N=64$

** all baseline and Week 4 values are shown as the mean (SD) over a 24-h period

All clinical symptoms showed statistically-significant improvement ($P<.05$) after 4 weeks of treatment with the PMNS patch. Decreased urgency incontinence episodes were accompanied by improvements in all three secondary endpoints. Reductions in voiding frequency and urgency episodes were highly significant. The increase in voiding volume was less than expected. No severe adverse events occurred. The majority of adverse events were mild (90.6%), and 76.6% involved skin reactions, all of which resolved.

Conclusions:

The PMNS patch appears to be an effective, noninvasive treatment for the symptoms of OAB, causing significant reductions in urinary frequency, urgency, and urge incontinence after 4 weeks of treatment.

References:

1. Nat Rev Neurosci 2008; 9:453–66
2. Am Fam Physician 2006; 74:2061–8
3. Int Urogynecol J 2010; 21:S467–74

Presentation Number: 144

INTRAVESICAL BOTULINUM TOXIN INJECTIONS FOR OVERACTIVE BLADDER SYNDROME-A COCHRANE REVIEW

J. DUTHIE[1], M. VINCENT[2], P. HERBISON[1], D. WILSON[1]; [1]Univ. of Otago, Dunedin, New Zealand, [2]Kew Hosp., Invercargil, New Zealand.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To identify all randomised controlled studies relating to the use of intravesical BTX for OAB in adults. To examine the evidence for BTX versus placebo and other treatments; to ascertain the optimal dose, formulation, and administration technique; and assess the safety of the treatment. To provide a robust meta-analysis of all relevant level one evidence.

Background:

Intravesical botulinum toxin (BTX) has become increasingly popular in the management of refractory overactive bladder syndrome (OAB). This Cochrane review is a substantive update of the original review of 2007 which examined the randomised controlled data on the safety and efficacy of intravesical BTX.

Methods:

We searched the Cochrane Incontinence Group Specialised Trials Register in 23 February 2010). The Register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL), and handsearching of journals and conference proceedings. All reference lists of selected trials and relevant review papers were searched.

All randomised or quasi-randomised controlled trials of treatment for OAB in adults in which at least one management arm involved intravesical BTX were included.

Where possible, data were pooled to provide a quantitative meta-analysis

Results:

19 studies were identified that met the inclusion criteria. Most patients in the studies had neurogenic OAB, but some included patients with idiopathic OAB. Little data could be pooled due to variation in study design. The number of participants in the studies was universally small.

All studies demonstrated superiority of BTX to placebo in terms of subjective symptoms and/or urodynamic measures. While lower doses of BTX (100-150U) appeared to have beneficial effects, larger doses (300U) may have been more effective and longer lasting, but associated with more side effects. Suburothelial injection had comparable efficacy to intradetrusor injection. The effect of BTX may last for a number of months and is dependent upon dose and type of toxin used. Patients receiving repeated doses do not seem to become refractory to BTX. BTX appeared to have beneficial effects in OAB that quantitatively exceeded the effects of intravesical resiniferatoxin. Intravesical BTX appeared to be safe and well tolerated; however, one study was halted due to a perceived unacceptable rate of urinary retention.

Although traditionally avoided, it seems the trigone may be injected with BTX without any objective evidence of vesico-ureteric reflux resulting.

BTX-B has a much shorter effect, usually less than 10 weeks, which may be useful in test-dosing patients.

Conclusions:

Intravesical BTX appears to be an effective therapy for refractory OAB symptoms, but little controlled trial data exist on benefits and safety. Further robust data are required on long term outcomes, safety, and optimal dose of BTX for OAB.

References:

A full list of references of included studies is included in the full text of the review which is in press.

Fig. 1. Forest Plot Showing Reduction in
Incontinence Episodes; BTX vs Placebo.
Right Shift Favours BTX

Presentation Number: 145

A NEW AETIOLOGY FOR OAB: INTRACELLULAR BACTERIAL COLONISATION OF UROTHELIAL CELLS

R. K. KHASRIYA[1], S. ISMAIL[2], M. WILSON[2], J. MALONE-LEE[1]; [1]UCL, London, United Kingdom, [2]Eastman Dental Inst. UCL, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To test the hypothesis that uropathogenic bacteria colonise urothelial cells in patients with OAB and not in controls using an assay that detected intracellular bacteria after eliminating extracellular contaminants.

Background:

There is good evidence of systematic failure to identify UTI in patients with OAB. Urinary inflammatory exudates in patients with OAB has been reported and re-confirmed as commonplace (1). A likely cause would be bacterial infection, but the associated symptoms favour mechanisms different to acute UTI.

There are good reasons to suspect chronic intracellular bacterial colonisation as the culprit in this pathology. In the murine model of urine infection, chronic infection can serve as the seed for recurrent infections that are resistant to short-term (10-day) treatment (2). Populations of E. coli can persist in the bladder for months on end, during which time they exist as a quiescent reservoir after invading and multiplying in the urothelium (2). Quiescence and infrequent mitosis, would give considerable antibiotic and immune resistance.

It has been shown that the culture of a concentrated suspension of urinary uroepithelial cells has proved extremely effective in isolating uropathogens from patients, in contrast to controls (3).

Methods:
We studied 23 women, mean age 56 (sd=17); 16 had OAB symptoms and provided a CSU; 7 asymptomatic female controls, average age 29 (sd=12), provided a CSU. An aliquot of urine was examined immediately by microscopy and the urinary white cells evaluated. An aliquot of urine was sent for routine culture with a threshold of 10^5 cfu/ml. An intracellular invasion assay on the shed epithelial cells was performed: The cell sediment was extracted by centrifuge at 800 g for 5 min. The deposit was incubated in cell culture media (Eagles Minimal Essential Medium) for 12 h to encourage confluence of bladder epithelial cells and bacterial growth. The cells were then incubated with gentamicin 200 μg/ml, lineozelid 200 μg/ml and amoxicillin 200 μg/ml for 24 h to kill all extracellular bacteria. During this process the preparation was washed three times and reconstituted. The death of extracellular bacteria was confirmed through culture. After 24 h, a sterile extracellular space was confirmed, and the cells were lysed using Triton X 0.1% and the viable intracellular bacteria where enumerated by culture.

Results:
The routine culture at 10^5 cfu/ml were reported as positive in 3 (19%) OAB patients, none of whom had pyuria. 15/16 (94%) of the OAB samples showed evidence of intracellular bacterial colonisation of the bladder epithelium and only 2/7 (28%) of the control specimens showed the same.

The figure illustrates the time course of the assay. The extracellular bacterial population fell to zero, on colony counts, during the incubation with three antibiotics. After the final wash Triton-x lysed the cells. This event was followed by a marked increase in the colony counts. The only explanation for this was colonisation from intracellular bacterial sources. Every stage of the assay had method controls that supported intracellular colonisation. The human controls supported the proposition that intracellular colonisation is a pathological process. The average colony counts post cell lysis were 1× 10^6 cfu/ml^-1 in patients. In the two positive control volunteers, these counts were 10^1 cfu/ml^-1.

Conclusion:
This is the first time that an intracellular colonisation of the uroepithelial cells has been incriminated in the aetiology of OAB. The implications are substantial.

References:
1. J.Urol., 17-3-2010, 183; 1843, 1847.
2. Antimicrob.Agents Chemother., 2010, 54; 1855, 1863.
3. Science., 4-7-2003, 301; 105, 107.

Presentation Number: 146

TECHNICAL PREFERENCES OF SURGEONS PERFORMING A SACROCOLPOPEXY PROCEDURE

R. BASSALY, M. MCCULLOUGH, D. HUSSAMY, K. DOWNES, L. HOYTE, **S. HART**;
Univ. of South Florida, Tampa, FL.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To determine the technical preferences of surgeons performing the sacrocolpopexy procedure for the treatment of pelvic organ prolapse.

Background:
Sacrocolpopexy remains one of the most effective surgical methods for restoring pelvic support. In addition to the traditional abdominal sacrocolpopexy, laparoscopic and robotic-assisted approaches have become more common. Although abdominal sacrocolpopexy has long-term success rates ranging from 93% to 100%, this approach is associated with a relatively higher blood loss and longer recovery time compared to newer minimally-invasive approaches [1]. Data suggests that laparoscopic sacrocolpopexy has comparable clinical outcomes to the open approach, but widespread adoption has been limited by the increased technical difficulty, longer operative times and steeper learning curve compared to the open technique [2, 3]. Robotic-assisted sacrocolpopexy offers some advantages over laparoscopy, including increased surgical dexterity and stereoscopic visualization, which may mitigate some of the challenges of adopting the laparoscopic approach, but operative times remain substantially higher. It is possible that specific sacrocolpopexy techniques have an effect on operative time and outcome. The purpose of this study is to report on the surgical preferences of the International Urogynecological Association (IUGA) members in the performance of the sacrocolpopexy procedure.

Methods:
The Institutional Review Board approved this study. This is an internet based survey of IUGA members. It consists of 46 questions, and was developed on Checkbox (Checkbox Survey Solutions, Inc., Watertown, MA). Questions in this survey included: surgical route (open, laparoscopic and robotic-assisted approaches), extent and methods of graft attachment, retroperitonealization of the surgical graft, and other technical aspects of the sacrocolpopexy procedure, as well as training and demographics of the surgeon population. Email invitations were sent to all IUGA members, inviting them to participate anonymously. The survey was available from December 2010 to January 2011. Data was compiled into a spreadsheet and descriptive statistics was performed using SPSS for Windows (version 19.0, IBM Inc., Chicago, IL).

Results:
There were 198 completed responses during the survey period. The majority of respondents were male 145 (73.2%). Most respondents practiced in North America (35.9%) or Europe (34.8%), and two-thirds listed their primary specialty as Urogynecology. Half of the respondents practiced in an Academic/teaching hospital setting, and over 67% completed fellowship training, with three-quarters completing advanced training in Urogynecology. Over 35% of respondents were in practice less than 10 years and 27.3% greater than 20 years. Ninety percent of the respondents stated they perform

sacrocolpopexy procedures in their practice. The breakdown of surgical route was: abdominal sacrocolpopexy (n=149), laparoscopic sacrocolpopexy (n=81) and robotic sacrocolpopexy (n=43).

Of those performing abdominal sacrocolpopexy, 67.8% reported the use of permanent sutures to attach the graft to the vaginal cuff/apex, 86% utilized permanent sutures to attach the graft to the sacrum and over 50% reported the use of 2 sutures at the sacrum. Of those performing laparoscopic sacrocolpopexy, 65.4% reported the use of permanent suture at the vaginal cuff/apex, 51% utilized permanent sutures to attach the graft to the sacrum compared to 40% who reported use of surgical tacks, and over 75% reported the use of 2–3 attachments to the sacrum. Of those performing robotic-assisted sacrocolpopexy, 72% reported the use of permanent suture to attach the graft to vaginal cuff/apex, over 90% utilized permanent suture to attach the graft to the sacrum with 65.1% reporting two attachment sites to the sacrum.

Regardless of surgical method (abdominal, laparoscopic or robotic-assisted), over 80% of the participants reported always retroperitonealizing the sacrocolpopexy mesh at the end of the surgical procedure. Participants also reported reduced blood loss, shorter hospitalization and longer operative time during laparoscopic and robotic procedures compared to open abdominal sacrocolpopexy, but no differences were reported in overall major complications.

Conclusion:

Surgical preferences and techniques for sacrocolpopexy are similar among IUGA members, regardless of the surgical route used. Survey participants report that laparoscopic and robotic-assisted sacrocolpopexy procedures tend to be associated with less blood loss and shorter hospitalization, but longer operative times than the abdominal approach.

References:

1. Surg Endosc. 2009;23(10):2390–4.
2. AJOG 2005;192:1752–8.
3. BJOG 2009;116:1251–7.

Presentation Number: 147

DOES CONCOMITANT LAPAROSCOPIC TOTAL HYSTERECTOMY INCREASE THE RISK OF SACROCOLPOPEXY MESH EROSION?

H. W. FISHER, P. M. LOTZE;
Women's Pelvic Hlth.and Continence Ctr., Houston, TX.

Consent obtained from patients: Not Applicable

Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To compare medium term mesh erosion rates after laparoscopic sacrocolpopexy with and without concomitant laparoscopic total hysterectomy (LTH).

Background:

Laparoscopic sacrocolpopexy has an objective cure rate of 78-100% (1). The risk of subsequent mesh erosion has a reported range of 1-10%. The rate of mesh erosion with concomitant hysterectomy varies from 2% to 27%, compared to a 1-5% risk of erosion without hysterectomy (1,2,3). Despite this apparent potential difference in erosion rates, the literature remains inconsistent with respect to a concomitant hysterectomy as a true risk for future erosion. In 2007, a retrospective review of 402 patients reported no significantly increased risk with concomitant LAVH (0.7% vs 2.3%, p = NS) (2). A retrospective study in 2010 reported a 23% risk with concomitant TVH compared to 5% in post-hysterectomy patients. The goal of our study is to determine if there is a difference in erosion rate when a concomitant LTH is performed with a laparoscopic sacrocolpopexy.

Methods:

Following institutional review board approval, a historical cohort analysis was performed on all patients undergoing a laparoscopic sacrocolpopexy, along with other indicated procedures, from January 2008–September 2010. Data was collected through chart review of both office and hospital records. Patients were divided into groups based on whether or not a LTH was performed concomitantly with the sacrocolpopexy. Laparoscopic hysterectomies were performed as described by Reich. Delayed absorbable suture used to close the vaginal cuff. All patients had one anterior and one posterior strap of Type 1 macroporous polypropylene mesh sutured to the vagina using a combination of six permanent and three delayed absorbable sutures. Pre- and postoperative POP-Q exams were recorded. Recorded demographic data included body mass index (BMI), medical history, tobacco use, menopausal status, estrogen use (HRT), prior incontinence or prolapse procedures (GU), and intra-operative blood loss (EBL).

Results:

A total of 263 patients were identified with 106 in the LTH group and 157 in the post-hysterectomy group. The mean follow-up was 8 months. Both groups were similar in parity (2.6), BMI (28.3 vs 27.6), medical history, preoperative POP-Q stage (stage 3), and EBL (82 ml vs 66 ml). The concomitant LTH group had a lower mean age (56.9 vs 61.9 years), menopause status (75% vs 94%), HRT use (12 vs 45%), and prior prolapse or incontinence procedures (5% vs 44%). The overall mesh erosion rate was 1.1% (3/263). The rates were statistically similar between the LTH group (n=2; 1.9%) and the post-hysterectomy group (n=1; 0.6%) (p<0.05). All erosions were noted to be remote from the vaginal cuff.

Conclusions:

The addition of a laparoscopic total hysterectomy, as an independent variable, does not increase the general low rate of post-operative mesh erosion in patients undergoing a laparoscopic sacrocolpopexy. This appears to be a more ideal approach for removal of the uterus given the increased erosion rates reported with some other routes of hysterecto-

my. Subsequently, a concomitant LTH, when indicated, can be considered at the time of a sacrocolpopexy.

References:

1.Am J Obstet Gynecol 2008;199:688.e1–688.e5

2.Journal of Minimally Invasive Gynecology 2008; 15:188–196

3.Int Urogynecol J 2011;22:205–212

Table 1. Demographic Data

	Concomitant Hysterectomy (n=106)	No Concomitant Hysterectomy (n=157)	p
Age	56.9±10.5	61.9±8.9	<0.05
Parity	2.7±1.1	2.6±1.2	0.5
Race			
Caucasian	87.7%	93.6%	
AA	1.9%	0.6%	
Hispanic	10.4%	5.1%	
Asian	0.0%	0.6%	
BMI	28.3±5.1	27.6±4.9	0.3
HRT Use	12.2%	45.3%	<0.05
Diabetes	14.2%	7.6%	0.1
Smoking	0.0%	0.6%	1.0
Menopausal	75%	94%	<0.05
Prior GU Procedures	5%	44%	<0.05
EBL(mL)	81.8±44.7	65.9±30.3	<0.05
Pre-op Ba	2.6±2.4	2.2±2.7	0.2
Pre-op Bp	−0.7±2.8	0.5±3.3	<0.05
Pre-op C	0.5±3.4	−1.8±4.6	<0.05
Pre-op stage	2.9±0.5	2.9±0.6	0.5
Mesh erosion	2(1.9%)	1(0.6%)	0.6

Presentation Number: 148

CHRONIC PESSARY USE IN PELVIC ORGAN PROLAPSE IN WOMEN

S. RAMSAY, L. TU, F. BOUCHARD;

Université de Sherbrooke, Sherbrooke, Canada.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

The main objective of this retrospective study is to evaluate whether long-term use of vaginal pessaries is an appropriate conservative treatment for women with pelvic organ prolapses.

Background:

Pelvic organ prolapse is a common condition, particularly among older women. Apart from surgical options, it can be managed conservatively, an attractive option for our aging population. Although the use of pessaries is common worldwide, there is no consensus on the use of different types of devices, the indications, nor the pattern of maintenance or replacement, and follow-up care due to lack of appropriate studies addressing these issues.

Methods:

From January 1998 to December 2010, 429 women with pelvic organ prolapse had a pessary trial at our institution. Prior to the trial, every woman underwent a thorough history and gynecological exam. Therapeutical options were explained to the patient, and if pessary was chosen, the trial was performed on the same day. Vaginal atrophy or constipation had to be treated prior to the trial. Patients received instructional documentation about pessary maintenance and were encouraged to use topical estrogen and mucolytic cream at home. A follow-up appointment was scheduled one month later. History and gynecological exam were repeated, and a maintenance regime for the pessary was chosen (self-maintenance, maintenance by nurses in regional clinics or by nurses in our own clinic). Additional follow-up appointments were then scheduled yearly, or before as patient needs. Data gathered included descriptive information regarding each patient, specific information concerning pessary use, incidence of vaginal erosions or other associated morbidities, final choice of treatment, and patient's satisfaction rate.

Results:

Average age at presentation was 71.1 9.7 years old. 50% of patients had had hysterectomy and 22% had had a prior prolapse surgery. Patients with previous hysterectomy, prolapse surgery, or multiple prolapses favored surgery as the final treatment. 62% (n=258) of women had a successful pessary trial, which was defined as a 1-month use of the pessary with subjective improvement of symptoms and no major complication. Median duration of pessary use was 35 months (1–136). 96% of women were satisfied or very satisfied with their pessaries. 66% (n=170) of patients could handle pessary by self-maintenance, while 23% (n=59) needed assistance from a regional nurse, and 11% (n=28) necessitated maintenance by our clinic nurses. Among these three groups, 71%, 61%, and 43% of the patients respectively continued using the pessary. Of these women, 12% (n=30) eventually used the pessary intermittently. Pessary self-maintenance was associated with a prolonged use of the pessary (38 months vs 30 months for the nurse group vs 27 months for the clinic group, p=0.021). Mucolytic cream use was also associated with a prolonged use of the pessary (38 vs 26 months, p=0.001). The overall erosion rate was 16% and was not associated with the degree of prolapsus. Constipation and longer duration of pessary use were associated with higher rates of erosions (23 vs 12%, p=0.027, and 45 vs 33%, p=0.015 respectively), while sexually active women had a significantly lower rate of erosions (7 vs 21%, p=0.007). Finally, contrary to our expectations, use of topical estrogen cream seemed to associate with a higher rate of erosions (25 vs 5%, p<0.001). However, older age was also associated with a higher rate of erosions (p<0.001), and older patients were more likely to use topical estrogen cream because of vaginal atrophy (p<0.001).

Furthermore, multivariate analysis using the forward-selection technique demonstrated that erosions are associated with older age (p=0.011), constipation (p=0.018), and use of topical estrogen cream (p=0.001). There was no major complication. 66% (n=170) of women who underwent a successful pessary trial are still using a pessary.

Conclusions:

Based on our experience, the pessary is an effective and safe alternative treatment for women with symptomatic pelvic organ prolapse. These long-term results show that patient's satisfaction is excellent and that the majority of women who underwent a successful pessary trial continue to use the pessary through time. There was no major complication related to the treatment after a median follow up of 35 months. Pessary self-maintenance regime appears to be an important aspect of pessary management as it leads to a prolonged use of the pessary and to the choice of pessary as the final choice of treatment. Finally, use of topical estrogen cream was associated with a significantly high rate of erosions, but this could be explained by older patients having more significant vaginal atrophy. This unexpected result warrants the need for further studies to evaluate this component of pessary management.

Presentation Number: 149

FAILURE OF VOIDING AFTER ANTERIOR COLPORRHAPY: WHAT IS THE OPTIMAL TREATMENT?

I. S. BAKKER, J. DEN BOON, H. W. VAN EIJNDHOVEN; Isala Klinieken, Zwolle, Netherlands.

Consent obtained from patients: Not Applicable

Level of support: Investigator initiated, no external funding

Work supported by industry: No

Objective:

Evaluation of patients who failed the voiding trial after prolapse surgery and treated by clean intermittent catheterization (CIC) or an indwelling catheter.

Background:

After vaginal prolapse surgery with anterior colporrhapy it is common to use an indwelling transurethral catheter to prevent over distension of the urinary bladder. Removing the catheter on the first day postoperatively is very effective in most cases. However, in a minority of the patients a longer period of catheterization is needed. It is unclear how these patients should be treated.

Methods:

We evaluated 146 patients who underwent prolapse surgery with anterior colporrhapy in 2010. At the end of surgery all patients received an indwelling catheter. On the first morning after surgery the catheter was removed and patients were encouraged to void as soon as possible. A successful voiding trial was defined as spontaneous voiding with a residual volume of less than 150 ml twice in a row within 48 h after removal of the catheter. In case the patient failed the programme she was discharged with CIC. This was continued until the residual volume was lower than 150 ml according to the standard protocol. In this period the patient was accompanied by a specialised nurse, who had daily contact by telephone or email with the patient. If the patient was unable to accomplish CIC, she received an indwelling catheter for 7 days. After this period the catheter was removed at our department and a new trial of voiding was executed.

Results:

Of all the patients, 21 (14.4%) failed the programme. Of this group 9 (43%) were discharged with an indwelling catheter and 12 (57%) with CIC. Patients with an indwelling catheter reached normal micturition after 19 (6–50) days postoperatively and patients using CIC had a significantly lower mean of 7.5 (4–20) days (P<0.01) (table 1).

Conclusions:

After prolapse surgery with anterior colporrhapy, trial of voiding is not successful in 14.4% of the patients. In these cases CIC leads to a significantly shorter period of catheterization compared to the continuous use of an indwelling catheter. This emphasizes the importance to train these patients in CIC and accompany them intensively in the postoperative period after discharge.

Table 1

	N	Mean days of Catheterization
CIC	12	7.50 (SD ±5.09)
Indwelling Catheter	9	18.89 (SD ±15.86)*

* p <0.01; independent T-test

Presentation Number: 150

SHORT TERM EFFICACY AND SAFETY OF A SINGLE-INCISION MESH (PROSIMA) FOR THE TREATMENT OF PELVIC FLOOR PROLAPSE

A. D'AFIERO[1], G. A. TOMMASELLI[2], F. BASILICA[3], P. AFFINITO[4], D. STANCO[5], C. NAPPI[6];
[1]Ospedale S.Maria della Pietà, Casoria, Italy, [2]Univ. of Naples Federico II, Naples, Italy, [3]Dip. Materno-Infantile Napoli NA2 Nord, Naples, Italy, [4]Ospedale SS. Annunziata ASL NA1, Naples, Italy, [5]Ospedale Buon Consiglio Fatebenefratelli, Naples, Italy, [6]Univ. Federico II, Naples, Italy.

Consent obtained from patients: Yes

Level of support: Not Applicable

Work supported by industry: No

Objective:
To evaluate the intra-operative and short-term efficacy and safety of a single incision mesh device associated with a vaginal support device for the treatment of moderate symptomatic anterior and posterior vaginal wall prolapse.
Background:
The use of prosthetic materials seems to have improved surgical outcomes for pelvic organ prolapse and reduced the number of recurrences. On the other hand, the use of synthetic meshes, for different reasons, seems not to be suitable for patients affected by moderate pelvic organ prolapse (symptomatic stage II–III). Moreover, it has been suggested that synthetic meshes may have high incidence of specific complications, such as mesh shrinkage, erosion/exposure and vascular and organ lesions caused by the blind trans-obtutrator and trans-gluteal passages of trocars. To identify a simple method for the surgical management of symptomatic moderate anterior and/or posterior vaginal wall prolapse, a type I polyprolylene mesh with reduced size has been developed (Prosima, Ethicon Women's Health and Urology, NJ, USA). This mesh is introduced via a single incision technique, and with a real tension-free approach without fixation points.
Methods:
In this prospective study, we enrolled 22 patients affected by anterior or posterior vaginal wall prolapse. Inclusion criteria were: moderate symptomatic anterior or posterior vaginal wall prolapse (stage II-III) as diagnosed by PoP-Q staging; eligibility for surgical procedures (ASA≤2). Exclusion criteria were: stage IV pelvic organ prolapse, apical defect, obstructed defecation, contraindication to surgical procedures (ASA>3); diabetes; immunodeficiency. Primary end-point was post-operative PoP-Q score, with success defined as a PoP-Q score≤1 in all compartments. All patients signed an informed consent. Before the procedure, patients underwent gynecologic and proctologic examinations, and pelvic ultrasonography, and QoL questionnaire were completed. All patients received spinal anesthesia, perioperative antibiotic prophilaxy, and underwent anterior (n=11) or associated anterior/posterior (n=11) Prosima implant. Briefly, after infiltration of the vaginal wall with vasocontricting solution and colpotomy, the paravesical and/or pararectal spaces are opened and the ischiatic spine identified. Using two different introducers (one for the anterior and one for the posterior mesh), the arms of the mesh are positioned immediately anterior and above the ischiatic spine (anterior) or on the sacro-spinous ligament 2 cm medially from the ischiatic spine (posterior). The mesh is then stitched to the cervical ring and to the bladder neck and/or the perineal body. After completing the colporraphy, a vaginal support device (VSD) is tailored to the vaginal size and positioned into the vagina. Connected to the device is a balloon that is filled with air to act as vaginal packing. The balloon is deflated 24 h after surgery and removed, while the VSD is left in place for 21–28 days. Operative times, blood loss, and perioperative complications and VAS score for pain the day after surgerywere recorded. At the follow-up visits (6, and 12 months after the procedure), PoP-Q score, QoL questionnaires, VAS score for pain and tolerance of the VSD and the onset of complications were evaluated. Differences in PoP-Q scoring were evaluated using the Wilcoxon test. The other variables displayed a normal distribution and a Student's t test for coupled samples was used. Statistical significance was set for a P value of .05
Results:
Median follow-up time was 6 months [95%CI 4.7–7.2], with a maximum follow-up time of 12 months and a minimum of 3 months. Mean age was 49.1 years (range 38–74), 18 patients (90%) were postmenopausal and 4 were on hormonal replacement treatment (22.2%). During the procedure, only one case of bleeding >200 ml was observed and two vaginal injuries were recorded. Post-operative complications were a case of vaginal hematoma, one case of urinary tract infection and one case of vaginal infection. We did not observe any case of mesh erosion. Using the definition of cure, 95% of patients were objectively cured, with only one failure (stage III cystocele and rectocele in the same patient). QoL scores were significantly lower three months after the procedure. Mean VAS pain score was 2.5±1.1 24 h after the procedure, while mean VSD tolerance VAS score was 8.5±2.3.
Conclusions:
Correction of anterior and posterior vaginal wall prolapse using the tension-free, single incision Prosima device seems to be feasible with good, short-term anatomical results and with limited intra- or post-operative short-term complications. The number of patients is limited and the follow-up is short and thus no definitive conclusions may be drawn. Nevertheless, this cohort may represent a starting point for larger studies evaluating the effect of this new type of mesh.

Presentation Number: 151
FACTORS AFFECTING WOMEN'S OPTION IN MANAGEMENT OF PELVIC ORGAN PROLAPSE
S. CHAN, R. CHEUNG, A. YIU, L. LEE;
The Chinese Univ. of Hong Kong, Hong Kong, Hong Kong.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
Pelvic organ prolapse (POP) is common in women. The management can be conservative, using vaginal pessary or

surgery but the option of management could be varied by different factors.

Background:

This study aimed at studying the factors that could affect women's option in the management of POP.

Methods:

This is a prospective observational study. Women presented with pelvic organ prolapse with no treatment received at their first consultation were recruited. They filled in the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) before the consultation, followed by history taking and assessment on the type and stage of prolapse according to the Pelvic Organ Prolapse Quantification by gynecologist. Those who had concomitant urinary incontinence had urodynamic study with prolapse reduced using vaginal ring pessary to detect for presence of urodynamic stress incontinence (USI). Pros and cons of conservative management, vaginal ring pessary or surgery were explained to them. Women could have vaginal ring pessary while awaiting surgery. They were followed up in every 4–6 months to review their condition and decision of management. Management would be changed upon request of the women. The management that they have undergone or chosen was evaluated at the time of this report. Chi-square test and one-way between-groups ANOVA was used.

Results:

From September 2008 to May 2010, a total of 292 women were recruited. Their age was 60.5 (SD 10.9) and parity was 3.2 (SD 1.5). Overall, 54 (18.5%), 163 (55.8%), 75 (25.7%) had stage I, II, III or above prolapse respectively; and 260 had urodynamic study performed. The mean follow up was 15 (SD 7.2) months. Age, parity and being sexually active of the women were not associated with the treatment options. Stage II or above POP, concomitant USI, greater symptoms distress according to PFDI and more impaired quality of life (QOL) based on PFIQ were associated with surgical treatment. History of complications using vaginal ring pessary was also associated with surgical treatment.

Conclusions:

More severe POP, greater symptoms distress, more impaired QOL and history of complications using vaginal ring pessary were associated with surgical treatment for women with POP.

Table 1. Factors affecting women's option in management of pelvic organ prolapse

	Conservative	Vaginal ring pessary	Surgery	P-value
	N=83	*N*=56	*N*=153	
Age at first consultation	60.2 (11.6)	62.0 (10.3)	60.1 (10.7)	0.53
Parity	3.2 (1.8)	3.2 (1.5)	3.2 (1.4)	1.00
Sexually active	30 (36.2%)	22 (39.3%)	47 (30.7%)	0.72
Type of prolapse				0.01
Uterine prolapse	69 (83.1%)	55 (98.2%)	139 (90.8%)	
Vaginal vault prolapse	14 (16.9%)	1 (1.8%)	14 (9.2%)	
Staging of prolapse				
Stage II or above	49 (59.0%)	48 (85.7%)	141 (92.2%)	<0.001
Stage III or above	6 (7.2%)	11 (19.6%)	58 (37.9%)	<0.001
Presence of stage II or above prolapse of the different compartments				
Anterior	44 (53.0%)	12 (21.4%)	124 (82.7%)	<0.001
Apical	15 (18.1%)	31 (55.4%)	108 (70.6%)	<0.001
Posterior	10 (12.0%)	11 (12.8%)	56 (36.6%)	<0.001
Concomitant USI	21 (31.8%)(*n*=66)	10 (22.2%) (*n*=45)	64 (43.0%) (*n*=149)	0.03
PFDI scoring	194.2 (156.0)	179.8 (155.7)*	245.2 (180.0)*	0.02
PFIQ scoring	130.8 (198.0)	100.5 (143.1)*	180.8 (208.8)*	0.02
History of complications on ring pessary	21 (25.6%)	9 (16.1%)	86 (56.2%)	<0.001

* $p=0.02$ when compared vaginal ring pessary group to surgery group

Presentation Number: 152

OUTCOME OF ANTERIOR AND POSTERIOR TRANSVAGINAL MESH REPAIR FOR PELVIC ORGAN PROLAPSE: AN OBSERVATIONAL STUDY

K. JANSSEN, C. CHARANGAT, M. M. VERNOOIJ, J. H. SCHAGEN VAN LEEUWEN, H. S. THE;
Sint Antonius Ziekenhuis, Nieuwegein, Netherlands.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aims of this study were to find out the safety and efficacy of transvaginal mesh repair for pelvic organ prolapse, in the short and long term.

Background:

Pelvic organ prolapse is a common problem in women. The estimated prevalence of pelvic organ prolapse stage≥2, according to the Pelvic Organ Prolapse Quantification (POPQ) system, is about 40%, occurring mainly in parous women. Traditional prolapse repair procedures have high failure rate, about 30% of patients need surgery for residual prolapse. For this reason, surgery with implantation of mesh or graft materials was introduced. Transvaginal mesh repairs are relatively new techniques, not much is known about the long term results and complications. At median term, transvaginal mesh repair appears to be a safe and effective method for the treatment advanced and residual prolapse.

Methods:

All procedures of trans-vaginal mesh repairs that took place in a pelvic floor unit of a large district general hospital in the centre of the Netherlands, during the period from January first 2009 to December 31st 2010, were included. Procedures were done using both GYNECARE PROLIFT® Total, Anterior and Posterior Pelvic Floor Repair Systems and American Medical System, Inc. Elevate® Prolapse Repair System. Principal outcome measures were subjective cure and anatomic cure (stage 1 or lower), assessed by the POPQ system. Data were obtained from electronic patient records. Patients were enquired about symptoms of urogenital dysfunction before and after the operation, using a standardised questionnaire. Patients were followed-up routinely at six weeks at the out-patient department and longer if indicated. All patients received telephonic consultations at six months and yearly intervals.

Results:

24 and 42 patients were operated using PROLIFT mesh and Elevate mesh respectively. The mean period of follow-up was 12± 8,5 months. Mean age was 65,3. 97% of patients were operated for residual prolapse. All patients had prolapse equal to POP-Q stage 2 or more. Most patients (90.9%) had a prolapse equal to or more than stage 3. All patients had symptoms of urogenital dysfunction. Mean operation time and intra-operative blood loss was 73± 34 min and 116 (range 10–700) millilitres respectively. Intra-operative bladder and rectal injury occurred in 3.0% and 1.5% respectively. In the post-operative period 4.5% of patients experienced retention of urine, 3.0% had a urinary tract infection and 3.0% had secondary haemorrhage. At 6 weeks follow-up no anatomic failure was found in the operated compartment. The residual prolapse rate was 6.1%, in a period ranging from six months to one and a half years, most of them (75%) occurred in other compartments. Preoperative symptoms of prolapse, stress incontinence, urge incontinence, overactive bladder, dyspareunia and constipation were cured in 84.8%, 60.0%, 77.8%, 80.0%, 77.8% and 61.5% respectively. Only one patient had an erosion, which was detected as early as 6 weeks post-operative after PROLIFT Total. De novo stress incontinence, urge incontinence, overactive bladder, dyspareunia and constipation occurred in 19.7%, 4.5%, 7.6%, 1.5% and 6.1% of patients respectively.

Conclusions:

We demonstrated good subjective and anatomical cure in advanced and residual pelvic organ prolapse after trans-vaginal mesh repair at medium term. Good improvement of other symptoms of pelvic floor dysfunction was also observed. In our study population, the risk of erosion was low and was seen within 6 weeks post-operatively. The incidence of de novo stress incontinence was about 20%, which is in the lower range of what is quoted in the literature. Longer term follow-up will be continued.

References:

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Presentation Number: 153

VAGINAL REPAIR WITH POLYPROPYLENE MESH VERSUS TRADITIONAL COLPORRHAPHY FOR PELVIC ORGAN PROLAPSE: LONG TERM FOLLOW UP

A. BONDILI[1], N. SIRAJ[1], J. COOPER[2];
[1]Univ. Hosp. of North Staffordshire, Stoke on Trent, United Kingdom, [2]Univ. Hosp. of North Staffordshire, Stoke on trent, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To compare vaginal repair augmented by mesh (Avaulta ™ and Plus ™ Biosynthetic support system Bard) with traditional colporrhaphy for the treatment of pelvic organ prolapse.

Background:

There are many randomised controlled trails and observational studies on different vaginal mesh systems, mostly with short-term outcomes . We report the outcomes of mesh repair (Avaulta™ and Avaulta plus ™ biosynthetic support system) compared with traditional repair documenting long term outcomes of up to 3 years.

Methods:

It is a single centre prospective cohort observational study done in urogynecology unit at a university hospital in the united kingdom. We prospectively recruited patients undergoing mesh (n=41) and traditional anterior and posterior colporrhaphy (n=42). the validated international consultation on incontinence modular questionnare—vaginal symptoms (ICIQ - vs) (3) questionnaire was filled in the clinic pre operatively and postal questionnares were sent up to 3 years post operatively. For each different symptom effect on quality of life (qol), severity was assessed using a visual analog scale (vas) of zero to ten. In the mesh group, 40 women responded (97.5%) and there was a response from all women in the repair group.

Results:

At follow up in the mesh group, 1 (2.5%) out of the 40 women had symptoms of prolapse. in the standard repair group at follow up, 3 (7%) out of the 42 women had mesh repair in the same compartment. Pre operatively 12 (57%) out of 21 women who had posterior avaulta needed to digitate the vagina to empty their bowels. At follow up, only 2 patients (9.5%) still needed to digitate the vagina to empty their bowels. In the repair group 4 (28%) out of 14 who had posterior repair needed to digitate the vagina to empty bowels initially, and at follow up, none of them had these symptomss. Pre operatively, 22 (55%) out of 40 in the mesh group had dragging pain vaginally. At up to 3 years follow up, only one (2.5%) had this symptom. in the repair group pre operatively, 31 (74%) out of 42 patients had a dragging pain vaginally and at 3 years follow up only 11 (26%) had this symptom. In the mesh group pre operatively 16 (40%) out of 40 patients had a dry vagina. At follow up only 2 (5%) patients had a dry vagina. In the repair group pre operatively, 14 out of 42 (33%) patients had a dry vagina and at follow up this was reduced to 7 (17%) patients (table 1). The change in the mean symptom score from pre - op to 3 years in the mesh group is −18.75 compared to no mesh −12.88 with a p value of 0.27815 (table 2).

Conclusion:

In this study, vaginal surgery augmented by mesh had significantly better results with regards to the symptoms of dragging pain and a dry vagina. There was no statistical difference in actual prolapse symptoms. Overrall quality of life is much improved in mesh compared to no mesh (Fig. 1). Also worthy of note, 30% of patients undergoing mesh repair were having the surgery as a secondary operation.

Table 1

Symptoms	Pre op to 3 years Avaulta number with no symptoms total N=40	Pre op to 3 years No mesh number with no symptoms total N=42	P-value
Lump in or out of the vagina	**−39**	**−39**	**0.6441***
Digitation Empty Bowels	**−10**	**−4**	**1***
Dragging pain	**−21**	**−20**	**0.0204*#**
Dry vagina	**−14**	**−7**	**0.0662***

•

* Fishers Exact test ** Students T-test

A negative change indicating improved symptoms or quality of life

Table 2

	Mesh	No Mesh	P value
QOL Mean change from pre operative to 3 years (SD)	**−18.75 (9.867)**	**−12.88 (12.065)**	**0.304****

•

** Students T-test

•

A negative change in score was observed from baseline to 3 years after surgery indicating improved symptoms or quality of life

Fig. 1 Interference with overall quality of life (VAS 0–10) (Image)

References:

Int Urogynecol J Pelvic Floor Dysfunct 2008 Dec;19(12):1611–1616.

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Presentation Number: 154

CURRENT PRACTICES FOR ASSESSING AND SURGICALLY TREATING POP AMONG IUGA MEMBERS

P. MOURTIALON[1], P. SAGOT[1], L. FILIPUZZI[1], S. DOUVIER[1], R. DE TAYRAC[2];
[1]Bocage Univ. Hosp., Dijon, France, [2]Caremeau Univ. Hosp., Nîmes, France.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objective:
The aim of this study was to analyze pelvic reconstructive surgeon current practices for assessing and surgically treating pelvic organ prolapse.

Background:
Main objective of POP surgery is to treat symptoms experienced by patients with the lowest possible morbidity. Many surgical techniques are currently available, indicating that there in not one good approach but different surgeries depending of the patient. The use of mesh by laparoscopic and vaginal routes is recent weapon to help our patients. It's a real challenge for one single surgeon to master all the techniques and some cases are very difficult to manage requiring different specialist advice.

Methods:
A questionnaire has been built to explore current practices and validated by a panel of expert surgeons. Then, an internet survey has been sent by e-mail to the 2554 IUGA members. After the first 30 responses, several modifications have been done because of misunderstanding in the website design. In total, each member received three e-mails.

Results:
381 questionnaires from 51 countries were available for analysis (response rate 14.9%). Among responders, 67.2% (256/381) were male, 55.9% (213/381) urogynecologist and 39.9% (152/381) gynecologist. Responders spend on average 41% (from 3% to 99%) of their medical activity to POP management. The POP-Q system is the most used anatomical classification. Validated questionnaires for prolapse-related symptoms and quality of life are routinely used by only 37% (141/381) and 32.2% (123/381), respectively. Ultrasound and urodynamics are directly performed by 37.8% (144/381) and 62.7% (239/381) of responders, respectively.

Vaginal route is preferred by 76.3% (291/381) of the participants. Among responders, 46% perform vaginal surgery with a mean number of procedures of 99 per year (range 10–750). 77% (294/381) of the surgeons use mesh by vaginal route, with a majority of kits using non absorbable mesh. Technically, transobturator mesh and fixed mesh to the sacrospinous ligaments are the most used techniques. Mesh approaches seem to be a new relevant option for stage 3 or 4 POP and after failure, but not in first-line. Plication is still use for traditional repair. Robotic-assisted laparoscopic is not a very common technique. Systematic hysterectomy or systematic treatment of the three compartments is not the rule.

Conclusions:
Several biases exist in this study but in our knowledge this is the larger study about surgical practices in POP treatment. Surgeons have emphasized that there is not one but many different prolapse and they tried to accommodate the techniques to the patient.

Presentation Number: 155

INTRAOPERATIVE ULTRASONOGRAPHY USING A LINEAR ARRAY PROBE IN THE TRANSVAGINAL MESH SURGERY FOR PELVIC ORGAN PROLAPSE

M. J. NOMURA, S. TERAMOTO, Y. SHIMIZU;
Kameda Med. Ctr., Kamogawa-city, Chiba, Japan.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To examine the role of intraoperative ultrasonography using a linear-array probe for safe and effective transvaginal mesh (TVM) procedure

Background:
Recently, the use of polypropylene mesh for the treatment of pelvic organ prolapse (POP) is becoming more common. The TVM technique is one of the most common mesh surgery for the correction of POP. Dissection of the vaginal wall and fixation of the mesh are important for the TVM procedure. It is known that a linear array probe is suitable for scanning superficial structure. Intraoperative ultrasonography using a linear-array probe may provides valuable information about the anatomy of pelvic organs. In the present study, we performed intraoperative ultrasonography during the TVM surgery.

Methods:
Between January 2010 and September 2010, 60 patients with POP (stage III or IV) were included in this study. The TVM surgery was performed according to the procedure reported by the French TVM group [1]. During the surgery, intraoperative ultrasonography was performed using a 9 mm diameter linear-array contact ultrasound probe (Aloka, Co. Ltd., Japan). At first, the thickness of vaginal wall was assessed by a linear-array ultrasonography. Then, hyrdodissection were monitored by real-time ultrasonography. Following hydrodissection, vaginal wall was evaluated by ultrasonography and then, dissection was performed. The position of the bladder neck was also evaluated by ultrasonography, and the anterior mesh was fixed on the bladder neck.

Results:

Tranvaginal and transrectal ultrasonography using a linear-array probe provided information about the anatomical relationships of the pelvic organs. Ultrasonographic measurement of vaginal wall thickness revealed 4.2 mm and 2.4 mm in the anterior and posterior compartment, respectively. Following hydrodissection, ultrasonography revealed vaginal wall, vesicovaginal and rectovaginal space, bladder, and rectum (Fig.1). The dissection of the vaginal wall was performed on the basis of ultrasonography. There were no bladder and rectum injuries. The position of the bladder neck could also be identified. The distal end of the anterior mesh was anchored to the anterior vaginal wall near the urethrovesical junction under guidance of ultrasonography (Fig.2).

Conclusions:

Intraoperative ultrasonograpny using a linear-array probe provided information the orientation of pelvic organs during TVM surgery. These findings suggest that the use of this method may lead to a safe and effective surgical procedure. This method may be useful as an educational tool for teaching pelvic surgery.

References:

1. Fatton B, Amblard J, Debodinance P, et al.: Tranvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh(Prolift TVM technique) a case series multi-centric study. Int Urogynecol J Pelvic Floor Dysfunct, 18 : 743–752, 2007.

Fig. 1

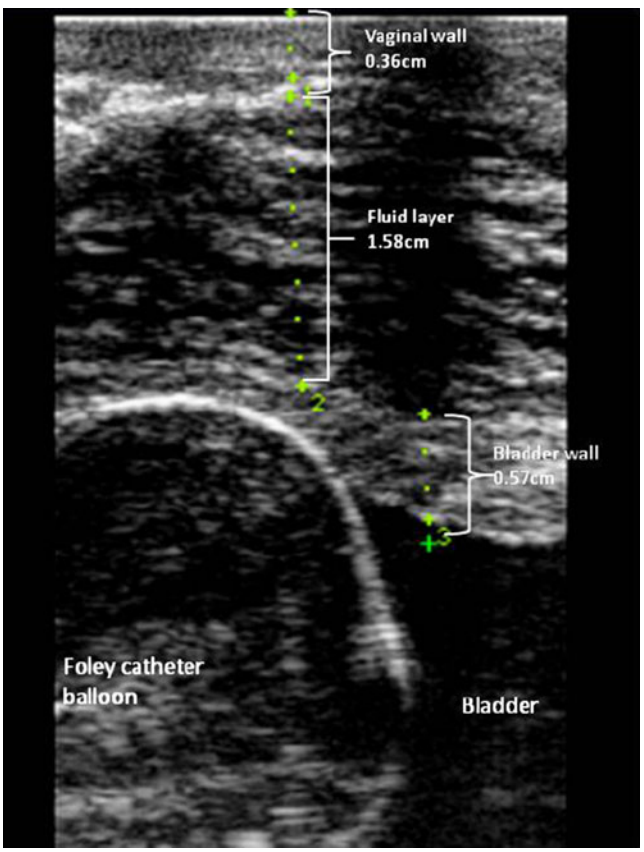
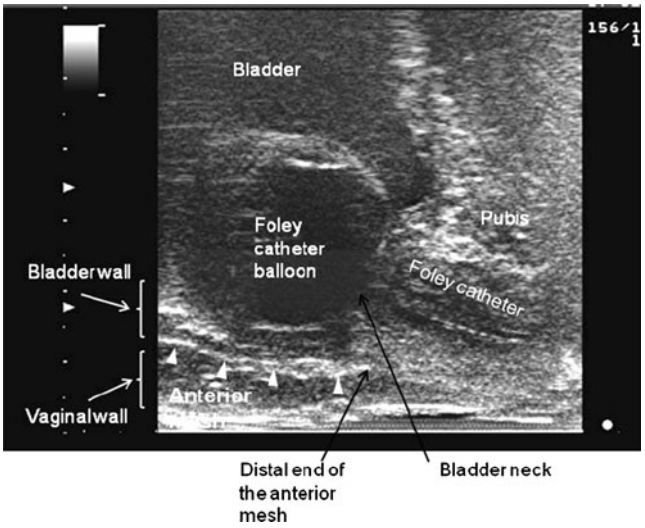


Fig. 2



Presentation Number: 156

ELEVATE® PROLAPSE REPAIR SYSTEM IN POP-SURGERY AND COMMONLY USED MESHES IN AUSTRIA: PROSPECTIVE DATA AND COMPARISON BETWEEN TWO NATIONALWIDE REGISTRIES—PRELIMINARY RESULTS

F. ROITHMEIER[1], J. ANGLEITNER-FLOTZINGER[1], F. OBERNDORFER[2], H. HUEMER[3], S. KROPSHOFER[4], W. STUMMVOLL[1];

[1]Hosp. of the Sisters of Charity, Linz, Austria, [2]Klinikum Wels-Grieskirchen, Grieskirchen, Austria, [3]Klinikum Wels-Grieskirchen, Wels, Austria, [4]Univ. Hosp. Innsbruck, Innsbruck, Austria.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

Since July 2010 we are using the Elevate® Prolapse Repair System for POP-surgery in our hospital. In addition to that we initiated a voluntary nationwide registry to gather data on peri- and postoperative complications and safety associated with this system. Now we present the preliminary results and compare our data to those, that had been collected by the Austrian Urogynecology Working Group within the Vaginal Mesh Registry (VMR) which did not contain Elevate® procedures before it was closed.

Background:

The Elevate® Prolapse Repair System is a total transvaginal approach to prolapse repair requiring only a single incision. Minimal blind needle passage and proven implant pathways are some of the advantages of this new mesh kit. The comparison to commonly used mesh-systems may help to evaluate this new system.

Methods:
Four gynecological departments in Austria are using the Elevate® system for prolapse repair participate in the Elevate registry (ER). Until now 50 patients received this mesh system for POP-repair. An online questionnaire (similar to the one used for the VMR) addressed the relevant uro-gynecologic history, current complaints and surgical details. Data were collected preoperatively as well as 3 and 12 months postoperatively. At that time patients were asked about bladder-, bowel- and sexual function. Patients and physicians scored their subjective satisfaction with the outcome. Demographic and clinical data were analyzed using descriptive statistics.
Results:
Data of 50 surgeries with the Elevate® Prolapse Repair System were compared to data of 696 procedures with another 11 different systems, mainly Prolift® devices. The median postoperative stay was 4 days in the ER vs. 5 days in the VMR. The main indication in our patients was the recurrent POP, only 4% (2) of the patients in the Elevate registry (ER) had no previous pelvic floor surgery vs. 51% (357) patients in the VMR. Only two perioperative complications have been reported in the ER (one foley catheter accidentally fixed by a suture, one hematoma with spontaneous regression in the anterior compartment), but no major complications. There was a major complication rate of 4% (27) in the VMR. Eight patients in the VMR required RBC transfusions vs. no one in the ER as well. 7% (50) of the patients scored >3 on a Visual Analogue Pain Scale on the day of discharge in the VMR, in the ER none scored >3..
Conclusions:
Despite the different dimensions of the two study populations the Elevate® system for prolapse repair seems to be safer and in our opinion easier to perform than other mesh kits.
References:
J Min Invas Gyn 2010; 7 abstract 406 AAGL, Lukban J et al. A Prospective Multicenter Study Evaluating Elevate Apical and Posterior for Treatment of Posterior and/or Apical Vaginal Wall Prolapse: 12 months follow up. IUGA Meeting 2010

Presentation Number: 157

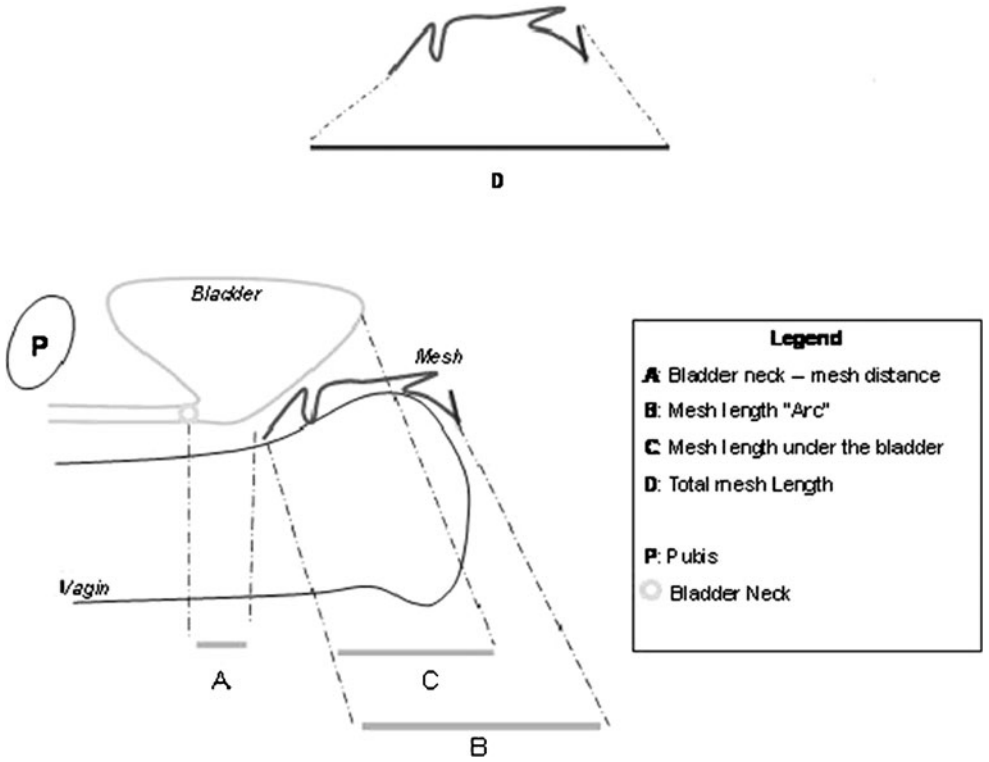
ULTRASONOGRAPHIC SCAN EVALUATION OF SYNTHETIC MESH USED FOR VAGINAL CYSTOCELE REPAIR COMPARING FOUR ARMS TRANS OBTURATOR TECHNIQUES TO BILATERAL ANTERIOR SACROSPINOUS LIGAMENT AND ARCUS TENDINEUS SUSPENSION, AT 1 YEAR FOLLOW UP

V. LETOUZEY, E. MOUSTY, S. HUBERLANT, O. POUGET, P. MARÈS, R. DE TAYRAC;
CHU Caremeau, Nimes, France.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
The main objective is ultrasonographic evolution of synthetic mesh at 1 year follow up and its correlation with clinical outcome.

Background:
Pelvic organ prolapse (POP) surgery benefits of new synthetic mesh and new surgical kit to perform surgery. Tension free meshes were placed with four arms trans obturator (TO), and a more recent one with bilateral anterior sacro spinous ligament and arcus tendineus suspension (SE).
Ultrasonographic scan shows synthetic mesh used in vaginal cystocele repair. Pelvic position and evolution of the mesh can be followed up after surgery. Dislodgement and contraction are pointed to be a part of mesh complication repair, for prolapse recurrence. Surgical procedure, define multi parameters to localize the mesh.
Methods:
Between January and March 2010, we included prospectively 50 patients, 20 with trans obturator polypropylene mesh Ugytex™ (Sofradi, COVIDIEN) (TO), and 30 with Pinnacle™ (Boston Scientific) (SE) mesh for vaginal cystocele repair.
The mesh was measured pre operatively (PO). Ultrasonographic scan was performed 2D/3D, intra vaginal and trans perineal, 3 day (D3) and 6 week (W6) and at 1 year (Y1) follow up. 3D mesh reconstruction and intra vaginal—trans perineal scan permit a double checking of measurements. We evaluated mid-sagittal length of the mesh, anatomic place, distance to bladder neck and mesh area. We defined the "arc" of the mesh, distance between the two most opposite points of the mesh under vagina. Clinical examination with POP-Q was done at each follow up.
We sought a correlation between clinical recurrence at 1 year follow up and ultrasound at 6 weeks.
Results:
All meshes were visualized.
A decrease in the total length is noticed for (TO) [W6 : 40+/−9 mm to Y1: 37+/−9 mm] not observed for (SE) meshes [W6 : 45+/−12 mm Y1 : 45+/−13 mm].
At 1 year postoperatively, the (TO) mesh correspond to 69% of the initial mesh measured by ultrasound at day 3 (Y1/D3) with an arcus measured at 32 mm (+/−8 mm) versus 88% for the (SE) mesh with an arcus of 40 mm (+/−9 mm) in average.
There is a better place for the spreading of the (SE) meshes.
The sagittal arcus at 6 weeks is a prognostic factor of its at 1 year because it no longer changes, (Y1/W6): (TO) 32 mm (+/−8 mm) and (SE) 40 mm (+/−9 mm) .
We have two cases of recurrent cystocele of grade 2 for (TO) mesh placement and one for (SE) prostheses. In these three cases, recurrence is located in the lower part of the anterior vagina (between mesh and bladder neck) (bladder neck mesh distance 19 mm +/−4 vs 4 mm +/−4, $P<.05$).
Conclusion:
Mesh (SE) does not decrease in size between W6 and 1 year compared with (TO). Ultrasound at 6 weeks appears to define a situation at risk of clinical recurrence by placement of the mesh relative to the bladder neck.
The type of prosthesis tension free fixation seems to predefine its evolution (size) in time
Mesh shrinkage was due partly to its method of installation.



Presentation Number: 158

OUTCOME AND ACCEPTIBILITY OF CONSERVATIVE MANAGEMENT OF UTEROVAGINAL PROLAPSE WITH VAGINAL PESSARIES

F. ROSS, J. COOPER;
Univ. Hosp. of North Staffordshire, Stoke-on-Trent, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To learn whether patients at a University Hospital in England who had a vaginal pessary for treatment of pelvic organ prolapse felt it relieved their symptoms, whether they experienced any complications and were satisfied with the service offered to them.

Background:

The prevalence of any degree of pelvic organ prolapse (based on examination) in women in the United States (aged 50–79) is 41.1%[1]. Once diagnosed, a decision needs to be made regarding the appropriate management. Non-surgical management includes pelvic floor rehabilitation and the use of a pessary. Surgery is used for more severe prolapse (which would not respond to conservative management), following unsuccessful physiotherapy and/or pessary trial or when women decline a pessary. Vaginal pessaries are a simple, non-surgical treatment modality for pelvic organ prolapse. They are offered as temporary management whilst a patient is awaiting surgery[2], a permanent solution for women unfit for surgery or who have declined it, or sometimes as a gauge as to how successful surgical repair is likely to be[3].

Methods:

Two hundred women who attended the pessary clinic at the University Hospital of North Staffordshire, England, from June 2009 onwards were sent an anonymous questionnaire by post. Questions were asked regarding the type of pessary they had in situ, whether they had complete, partial or no relief of symptoms, what complications, if any, they experienced and their overall satisfaction with the vaginal pessary. Satisfaction with the service offered was also asked about, including whether they felt they received enough information before they had their pessary and whether they were uncomfortable during insertion and removal.

Results:
Of the 200 women, 154 (77%) responded. 94 women (61%) reported complete resolution of symptoms, 53 (34.4%) partial resolution and 7 (4.5%) no improvement in symptoms following vaginal pessary insertion. Complications experienced included the pessary falling out (n=46, 29.9%), vaginal discharge (n=49, 31.8%) and vaginal bleeding (n=37, 24%). Of the 154 women who responded, only 8 (5.2%) went on to have surgical management of their prolapse. 134 women (87%) said that they would recommend a vaginal pessary to another woman as good management of a symptomatic pelvic organ prolapse.
33 women (21%) reported that they felt that they were not given enough information regarding vaginal pessaries prior to having one inserted.
Conclusions:
A vaginal pessary is a simple yet effective method of managing the symptoms of pelvic organ prolapse, with a high satisfaction rate. They can be used either as a temporary measure or more permanently. As a response to the number of women who felt that they did not receive enough information prior to having a vaginal pessary, an information leaflet for patients has been produced for issue in gynaecology clinic.
References:
1. Sun VW, Hampton BS. Epidemiology of Pelvic Floor Dysfunction. Obstetric and Gynecology Clinics of North America 2009;36(421–443)
2. Bash KL. Review of Vaginal Pessaries. Obstetrical and Gynaecological Survey. 2000;55(455–460)
3. Atnip SD. Pessary Use and Management for Pelvic Organ Prolapse. Obstetric and Gynecology Clinics of North America 2009;36(541–563)

Presentation Number: 159
INCIDENTAL SIGNIFICANT ENDOMETRIAL PATHOLOGY DURING VAGINAL HYSTERECTOMY
S. TANNUS, S. GINATH, T. LEVY, A. GOLAN, A. CONDREA; Wolfson Med. Ctr. and Sackler Faculty of Med., Tel-Aviv Univ., Holon, Israel.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To determine the risk of incidental premalignant and malignant uterine pathology at the time of reconstructive pelvic surgery for the purpose of improving the workup and decision making prior to pelvic organ prolapse repair and uterine preservation.

Background:
The recent advances in pelvic organ prolapse repair technique and materials allow the pelvic surgeons to conserve the uterus at time of pelvic floor surgery. However, many still hesitate to do so partly because of future risk for significant endometrial pathology. Unanticipated premalignant and malignant uterine pathology at the time of reconstructive pelvic surgery reported to be 2–2.6% (1, 2).
Methods:
Retrospective analysis of the pathological findings at the time of vaginal hysterectomy over a 20 year period in a single public tertiary medical center was carried out. Postmenopausal patients presenting with postmenopausal bleeding had a preoperative endometrial biopsy. All those with a preoperative diagnosis of malignant or premalignant endometrial pathology were excluded.
Results:
A total of 567 patients underwent vaginal hysterectomy and associated reconstructive surgery for uterovaginal prolapse during the study period. Eleven of the 567 (1.9%) patients had incidental premalignant or malignant uterine pathological findings. Of those, two, (0.4%), had endometrial carcinoma. All pathologies occurred among the postmenopausal patients and none in premenopausal patient. 515 patients in our cohort were postmenopausal, 8 of 480 (1.7%) patients without postmenopausal bleeding showed simple endometrial hyperplasia without atypia, and 2 (0.4%) with endometrial carcinoma stage 1. Only one of the 35 (2.9%) patients with postmenopausal bleeding had an incidental finding of simple endometrial hyperplasia without atypia, and no one with endometrial carcinoma (Figure).
Conclusion:
In our series, premenopausal women with normal or abnormal uterine bleeding patterns where not found to be at risk of incidental significant uterine pathology during vaginal hysterectomy.
In postmenopausal patients that have not experienced uterine bleeding, the risk of significant incidental uterine pathology is 2.1%. Since the majority of which being simple endometrial hyperplasia without atypia and the rate of endometrial carcinoma was 0.4%, we conclude that no additional preoperative evaluation should be performed in this group of patients.
In women presenting with postmenopausal bleeding and negative endometrial evaluation the risk of change in the final post operative diagnosis to premalignant or malignant condition is minimal, thus proper evaluation of the endometrium prior to surgery for uterovaginal prolapse can minimize incidental findings of uterine pathology in such cases.
References:
1. J Obstet Gynaecol Br Commonw. 1970 Dec;77(12):1137–9.
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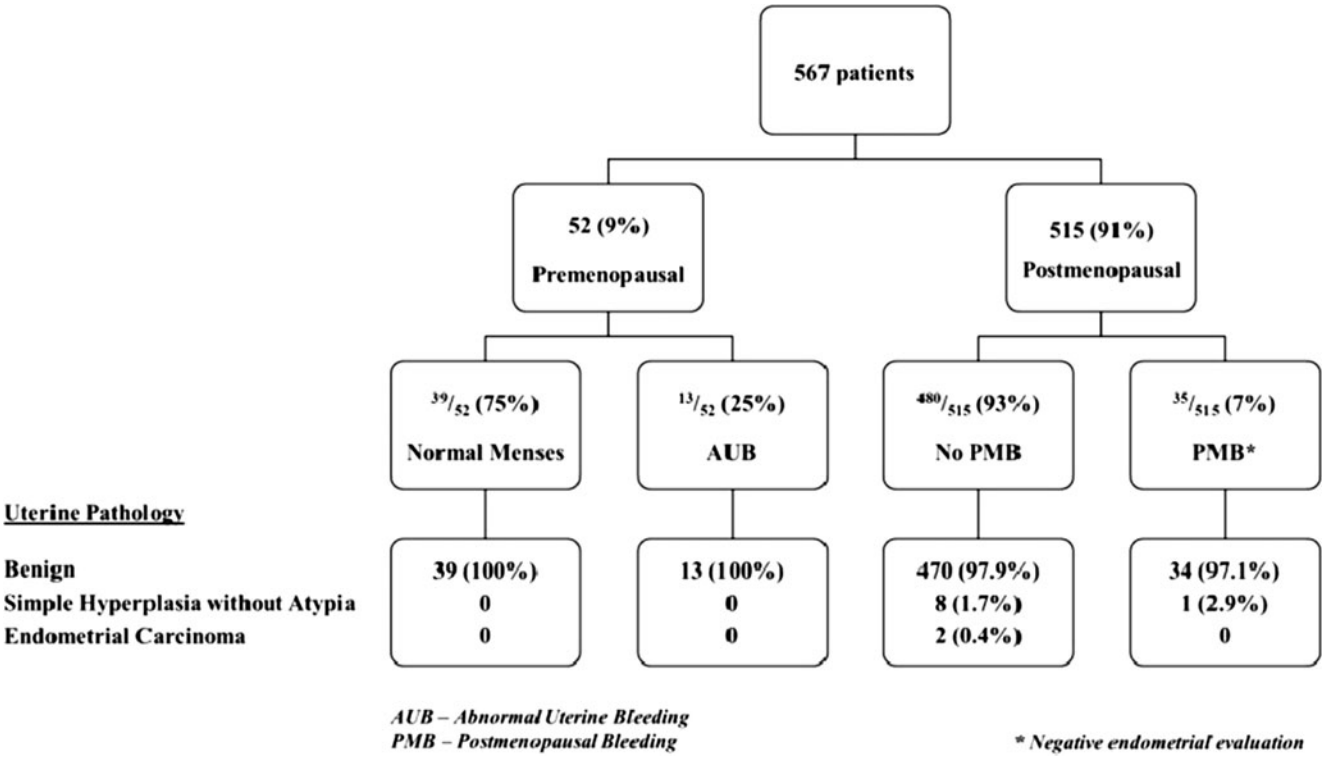

Presentation Number: 160

A NOVEL MEASUREMENT TOOL FOR THE REASONABLE MANAGEMENT OF VAGINAL PESSARIES IN PELVIC ORGAN PROLAPSE

S. NOJIMA[1], L. WANG[2], L. ZHOU[2], S. YOSHIKOSHI[1], C. UESHIMA[1], Y. FUJITA[1], N. NOZAKI[1], T. KANAEDA[1], Y. KAMIMURA[1], M. FUKUDA[1], M. EGAWA[1], S. TABATA[1];
[1]Tonami Gen. Hosp., Tonami, Japan, [2]Hei Long Jiang Hosp., Harbin, China.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To evaluate the effectiveness of the unique measurement tool versus conventional digital examination when the size of vaginal pessaries is determined in women with symptomatic pelvic organ prolapse (POP)

Background:
POP is still the most common indication for vaginal pessary usage. The use of mechanical devices such as pessaries is usually considered in women who for medical reasons cannot undergo surgery, desire to avoid surgery, or have a significant degree of prolapse that make other non-surgical approaches unfeasible [1]. Traditionally, the size of pessary is estimated after a digital examination. Once the approximate size is determined, they keep the same size of devices extend over a long period of time [2]. In many cases they are not changed by practitioners. After the insertion of undersized device, it falls out of vagina at once. The oversized devices make many complications-vaginal discharge, odor, bleeding, erosion and embedding. In order to use devices for long term, it is necessary to measure the accurate size of vagina, and choose the appropriate size of device [3].

Methods:
Women referred to a gynecology unit or female pelvic floor reconstructive centre of our hospital with symptomatic POP were offered a choice of vaginal pessary between March 2010 and Feb. 2011. The patients should be examined in the lithotomy position. If the patient opted to try a pessary, the fitting was done at the initial visit. Prolapse was measured with the Pelvic Organ Prolapse Quantification system. Vaginal caliber was estimated by digital vaginal examination and an appropriately sized ring pessary was selected and inserted. The ring pessaries (Wallace™) are available from 50 mm to 110 mm in Japan. After the initial fitting, the patient should return in two weeks and was taken the size of vagina with the improved inside calipers. After placement of device, some of them extruded from the vagina and then the large-sized ring was reinserted (group A). Women were followed up over three months. After removal of device an inspection of vagina should be carried out before insertion every three months. We found out discharge, bleeding, erosion and embedding in the vagina (group B) and no complication (control). These charts were searched for by database and by hand. Demographic details were gathered including age, parity, menopause, prolapse symptoms, physical examination, vaginal caliber, difference between inserted device size and calipers

measure, and rate of complications. Comparisons of groups were performed with "t-student"test for independent samples.

Results:

Of the 70 women with symptomatic POP, 54(77.1%) were treated with device and 16(22.9%) had chosen surgery; polypropylene mesh surgery: 13cases, colpoclesis: 2, vaginal hysterectomy with colporrhaphy: one case. 53 women after menopause choose to have a pessary and one is excluded for postpartum. Mean age was 73.5± 7.8 years and median parity was 2(range 1–4). Mean diameter of ring determined by the conventional digital examination was 65.8± 8.4 mm, and 63.0±6.7 mm measured by calipers. Of 53 women on the 2 weeks visit, 9(16.7%) lost the device (group A), one (1.9%) complained of de novo SUI to choose surgery and 24(45.3%) had no complication and complaint (control). After three months, complaints occurred in 19(35.8%); bleeding: 8 cases, erosion: 6, malodorous discharge: 2, discomfortable pain: one, and embedding; 2. In group A, mean size in initial fitting is 58.3±7.9 mm, 65.0±6.8 mm with calipers ($p<0.05$); group B: 72.2±6.7, 62.1±7.1 (n.s.); control: 64.0±6.0, 63.2±6.4 (n.s.)

Conclusions:

Digital examination method is conventional determination for device size and that is subjective and insecure. On the other hand, caliper gauge measurement is very simple and stable. The pessary is an excellent alternative for patients unwilling or unable to undergo surgery. For long-time usage of device, it is important to fit the appropriate size in the first visit. Using the caliper compass, practitioners are able to decide the accurate size of devices with confidence at one try. Pessaries can be offered as a safe long-term option for the management of POP.

References:

[1] A survey of pessary use by members of the American Gynecologic Society. Obstet Gynecol 2000; 95: 931–935.

[2] Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse. Am J Obstet Gynecol 2004; 190: 345–350.

[3] A simplified protocol for pessary management. Obstet Gynecol 1997; 90: 990–994.

Presentation Number: 161

TRANSVAGINAL SURGERY WITH BIOLOGIC AND SYNTHETIC MESHES FOR ANTERIOR VAGINAL WALL PROLAPSE—A SEVEN YEAR EXPERIENCE

V. VILHENA, R. MENDONÇA, R. SARMENTO, I. MATOS; Centro Hosp.ar de Setúbal, Setúbal, Portugal.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

The aim of this study was to evaluate the safety and efficacy of two different materials used in anterior vaginal wall prolapse surgical treatment—synthetic material and biologic (collagen) material.

Background:

To improve clinical outcomes for the correction of pelvic organ prolapse various new surgical techniques and materials have been proposed. Synthetic material has a cost-effective advantage but may result in significant complications. Biologic material is associated with fewer complications.

Methods:

Retrospective study, including patients with cystocele (stage 2 or 3), who underwent a surgical procedure with synthetic or biological material, from January 2004 to December 2010. The following parameters were reveiwed: age, parity, overweight, constipation, previous abdominal surgery, menopause state, operation time, perioperative and post-operative complications, recovery time, follow-up time and recurrencies. Statistical analysis was performed with IBM SPSS Statistics 19 software.

Results:

Ninety three patients were included in the study, 29 (31.2%) with grade 2 cystocele and 64 (68.8%) with grade 3. Mean patients' age was 66 years old (min=40 and max=88). Eighty seven women (93.5%) were post-menopause. Only 1 patient was nullipara. Thirty seven patients (39.8%) were overweighted, 29 (31.2%) had constipation, 21 (22.6%) underwent previous abdominal surgery. Stress urinary incontinence was present in 38 cases (40.8%). Synthetic meshes were used in 46 patients (49.5%) and biological meshes were used in 47 (50.5%). Seventeen patients (18.3%) underwent simultaneous surgery for benign gynaecologic pathology (vaginal hysterectomy or midurethral slings). Mean time of surgery was 65.1 min with synthetic meshes (min=27 and max= 90) and 64.8 min with biologic meshes (min=20 and max=90). Recovery mean time was 4.2 days in both groups (min=2 and max=7). Perioperative and post-operative complications were noted in 11 cases (23.9%) in synthetic meshes group (2 cases of mesh exposure requiring minor surgery, 3 cases of genitourinary infection, 2 cases of de novo urgency, 1 case of minor haemorrhage, 1 case of vaginal haematoma, 1 case of hip pain and 1 case of de novo stress urinary incontinence). In the biologic meshes group only 3 complications (6.4%) were reported (1 case of haemorrhage, 1 case of infection and 1 case of de novo urgency). Follow-up mean time was 18.3 months in synthetic meshes group (min=4 and max=47) and 20 months in biological meshes group (min=2 and max=44). Recurrence was reported in 4 cases in synthetic meshes group (8.7%) and in 3 cases in biologic meshes group (6.4%).

Conclusions:

There were no significant statistic differences in population characteristics (age, menopause state, parity, obesity, constipation, previous abdominal surgery and presence of other benign gynaecologic pathology) between both groups. Surgery mean time and recovery mean time were similar in the two groups. Perioperative and post-operative complications occurred most

frequently in synthetic meshes group with a statistic significant difference. Recurrence rates were similar in both groups. According to literature, both meshes are effective in treatment of cystocele, with similar mean surgical time, mean recovery time and similar recurrence rate. However, biologic meshes are associated with fewer complications than synthetic meshes.

Presentation Number: 162

IT IS POSSIBLE TO IDENTIFY SPECIFIC RISK FACTORS FOR SYMPTOMATIC STAGE II POP?: ANALYSIS OF 284 CASES

J. PIZARRO BERDICHEVSKY, V. MIRANDA, G. GALLEGUILLOS, C. VERA, R. CUEVAS, M. ARAMAYO, S. GONZALEZ, J. ORTIZ, A. MAJERSON;
Hosp. Dr. Sótero del Río/División de Obstetricia y Ginecología Facultad de Med., Pontificia Univ. Católica de Chile, Santiago, Chile.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
Describe the characteristics of patients with stage II POP symptomatic and asymptomatic, trying to identify risk factors for the presence of symptoms

Background:
Patients are classified as stage II when the distal portion of the prolapse is between −1 and +1 cm from the hymen. This definition allows to be encompassed in the same stage patients with prolapse, not beyond the hymen, and others in which this does occur, condition that not always is correlated with symptoms of bulge and/or vaginal weight. Thus, patients with stage II POP are of paramount importance, as it includes patients with and without surgical indication. Identifying specific risk factors for symptomatic patients seems relevant to design preventive strategies and/or non-surgical treatments allowing surgery differing in asymptomatic patients with stage 0, I or II who exhibit these risk factors .

Methods:
Retrospective case–control study of patients who were classified as stage II POP between January 2008 and December 2010. Cases were patients with symptoms of bulge or vaginal weight sensation (Sym), while controls were asymptomatic patiens (Asym). Were excluded patients with stage II apical POP and patients in whom there was not record of symptoms. Demographic and clinical characteristics were obtained from the hospital database. Clinical charts were reviewed to obtain: symptoms, gynaecological exam (including POPQ). Methods, definitions and units were according to the standards jointly recommended by the ICS and IUGA, except where specifically noted. Written informed consent was obtained from all patients before surgery.

Results:
In the study period, 1179 new admittances to our Unit were recorded. 284 were classified as anterior or posterior stage II, 175 were Sym and 109 Asym. Demographic and clinical characteristics are shown in Table 1 (all Tables values are expressed as number (percentage) or mean ± SD). Table 2 describe symptoms and urinary incontinence at physical examination. POPQ details are shown in Table 3.
Logistic regression, including variables with p value less than or equal to 0.09 in the univariate analysis, revealed that only the absence SUI at examination time, reduces the likelihood of being symptomatic of a stage II prolapse by almost 50% (OR 0,563 CI 0.337–0.943).

Conclusion:
62% of patients with stage II prolapse evaluated in our urogynecology unit have symptoms of vaginal bulge or weight. In a univariate analysis appear as risk factors for the presence of symptoms, HRT use, the presence of SUI at physical examination and as a protective factor that mostly prolapsed point be at −1 cm of the hymen. But when performing a logistic regression analysis, only the evidences of incontinence at examination persist as a independent risk factor. Future studies should evaluate the impact of preventive strategies in these patients, e.g. patients with stage II asymptomatic POP with SUI on physical examination.

	Sym	Asym	*p value*
Mean age (years)	54,6±10,1	56,2±10,8	0,51
Mean total parity	3,4±1,6	3,2±1,9	*0,06*
Mean Vaginal spontaneous birth	2,7±1,7	2,6±1,7	0,8
Median heaviest newborn weight	3781±600	3709±559	0,43
Instrumental Delivery	60 (34,3)	27 (24,8)	*0,09*
Post Menopause status	58 (33,1)	54 (49,5)	0,26
HRT usage	14 (8)	13 (11,9)	***<0,05***
Smoker's	51 (29,1)	31 (28,4)	0,93
Previous POP or incontinence surgery	17 (9,9)	7 (6,4)	0,33
Previous Vaginal Hysterectomy	8 (4,6)	2 (1,8)	0,22
Previous Abdominal Hysterectomy	16 (9,1)	11 (10)	0,79
Abdominal Hysterectomy or Vaginal Hysterectomy	24 (13,7)	13 (11,9)	0,66

	Sym	Asym	*p value*
Number of daily Pads usage	3±3	4±3	0,88
Nocturia (≥ 2 episodes of noctunal micturition)	110 (62,8)	74 (67,8)	0,48
Urgency or urgeincontinence	119 (68)	83 (76,1)	0,14
SUI Symptom	161 (92)	97 (89)	0,39
Inco tinence at physical examination	68 (38,9)	59 (54,1)	***<0,05***

		Sym	sym	*P-Value*
I a Classification		115 (65,7)	72 (66,1)	0,95
II p Classification		60 (34,3)	37 (33,9)	0,95
Mostly prolapsed point value	−1	16 (9,1)	19 (17,4)	***<0,05***
	0	108 (61,7)	69 (63,3)	0,78
	+1	51 (29,1)	21 (19,3)	*0,062*
Multicompartmental POP		51 (29,1)	34 (31,2)	0,71

Presentation Number: 163

DOES 3D/4D ULTRASOUND IMAGING OF THE PELVIC FLOOR ADD VALUABLE INFORMATION TO THE ASSESSMENT OF WOMEN WITH PELVIC ORGAN PROLAPSE?

A. DERPAPAS, G. A. DIGESU, G. VIJAYA, P. GALLO, C. HENDRICKEN, S. SYED, R. FERNANDO, V. KHULLAR; Imperial Coll. Hlth.care NHS Trust, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To investigate the role of 3D/4D ultrasound imaging in the assessment of women with pelvic organ prolapse (POP).

Background:

There is increasing evidence suggesting that women with POP have a significantly larger levator hiatal (LH) area compared to women of similar age and parity without prolapse.[1] The size of the urogenital hiatus (GH), measured during vaginal examination using the POP quantification system, has also been shown to correlate with the severity of POP.[2]

The biometric indices of the LH have been thoroughly studied in both asymptomatic and symptomatic women using magnetic resonance imaging (MRI), as well as 2D and 3D/4D ultrasound scan. Three- and four-dimensional ultrasound imaging has been shown to have good intra- and inter-observer reliability in the assessment of the LH, as well as a good correlation with MRI.[3] However, the role of 3D/4D ultrasound imaging in the assessment of women with POP is still contradictory.

Methods:

Women with symptoms of pelvic floor dysfunction presenting for urodynamics were recruited in a teaching hospital. Assessment included a detailed clinical interview and quantification of prolapse using the POP-Q system in the left lateral position. Prolapse was deemed significant if POP-Q stage was >= 2. All women underwent 3D/4D translabial ultrasound of the pelvic floor after voiding. Measurements of the LH anterior-posterior and transverse diameter, as well as area were taken at rest and maximum Valsalva in the axial plane, at the level of minimal hiatal dimensions. The dimensions of the GH in the axial plane, at the level defined by the line connecting the inferior most part of the symphysis pubis to the posterior fourchette, seen in the sagittal and coronal image, were also measured. Test retest reliability of the method used for measuring the GH was performed in 10 cases. The relationship between the size of GH and LH and the degree of prolapse and the predominant symptom was analysed with Mann Whitney-*U* test and one-way ANOVA test with post-hoc Bonferroni correction, respectively $p<0.05$).

Results:

Mean age of participants was 49 years (range 31–69) and median parity was 2 (range 0–6). With regards to severity of prolapse, 19/30 (63.3%) women had stage < 2 and 11/30 (36.3%) of women had stage >=2 prolapse. Mixed urinary incontinence (MUI) was the primary complaint in 16/30 (53.3%) women, followed by equal percentages of overactive bladder (OAB) (16.7%) and stress urinary incontinence (SUI) symptoms (16.7%). Prolapse symptoms was the main complaint in only 4 out of 30 women (13.3%).

The interclass correlation coefficient (ICC) values showed moderate to very good agreement (0.50-0.85) in all parameters measured. The LH anterior-posterior and transverse diameter, as well as the area was greater in women with significant prolapse than in those with non-significant prolapse, both at rest and maximum Valsalva. With regards to GH dimensions, women with significant prolapse had significantly wider transverse diameter at rest and maximum Valsalva than women with non-significant prolapse. There was no association between GH and LH size and presenting symptoms of pelvic floor dysfunction.

Conclusions:
Urogenital and levator hiatus size is significantly greater at rest and at straining in women with significant pelvic organ prolapse. However, this difference in size does not associate with the severity of prolapse symptoms as perceived by patients. Although 3D/4D pelvic floor ultrasound is a useful tool for depicting different types of prolapse, whether it can improve the diagnostic value of POP-Q system in assessing the severity of prolapse remains equivocal.

References:
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2.Obstet Gynecol 1998; 91: 364–368
3.Int Urogynecol J Pelvic Floor Dysfunct 2008; 19: 227–235

Presentation Number: 164

"REMEEX" RE-ADJUSTABLE SLING PROCEDURE: OUTCOMES AND SAFETY PROFILES.

E. KAPLAN;
Ctr. for Advanced Gynecologic Surgery, Walnut Creek, CA.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To investigate the outcomes and safety profiles of modified TRT (Tension Free Re-adjustable Tape, Remeex, Neomedic) for the treatment of primary and recurrent SUI.

Background:
Besides recent achievements in the treatment of stress incontinence (SUI) with mid-urethral sling procedures, 15–25% of patients remain incontinent after surgery and success rate deteriorates with time to 40% - "completely dry rate". Also up to 10% of patients develop voiding dysfunctions. Unfortunately, most of slings don't allow readjustment of its position/tension after the initial placement. In contrary, modified "Remeex" re-adjustable sling procedure not only allows for immediate adjustment of the position/tension of the sling in closest to physiological conditions but also allows for delayed re-adjustment in case of failure.

Methods:
300 consecutive women with urodinamically confirmed SUI undergone TRT - Remeex procedure. **Group - I:** 204 - primary SUI - "naive" patients. **Group - II**: 96 - recurrent SUI - h/o multiple previous SUI procedures. Length of the follow up was between 2 and 42 months after the surgery. Preoperatively we used objective measures (cough test, UD) and postoperatively patients' self-reported impression of improvement. Success was defined as "completely dry rate". Significantly improved was defined as leakage x1 per week. First 80 patients had TRT-Remeex regulator placed supra-fascialy. Next 220 patients had TRT-Remeex regulator placed under the abdominal fascia but over the rectus muscles tendon instead of recommended by company supra-fascial placement.

Results:
Group - I: 96.6% (*N*=197) primary SUI - "naive" patients were cured with primary Remeex placement. 2.5% (*N*=5) patients failed within f/u period and underwent delayed re-adjustment and were cured thereafter (Adjusted cure rate 99.1%). 0.9% (*N*=2) reported significant improvement after primary Remeex placement but could not be readjusted without producing retention. **Group - II**: 88.5% (*N*=85) patient with h/o multiple previous SUI procedures were cured with primary Remeex placement 9.4% (*N*= 9) patients with h/o multiple previous SUI procedures failed within f/u period and underwent delayed re-adjustment and were cured thereafter (Adjusted cure rate 97.9%). 2.1% (N=6) reported significant improvement after primary Remeex placement but could not be readjusted without producing retention. **Complications:** Prior to use of modified technique when regulator was placed over the fascia, 2/80 (1.2%) patients developed infectious abscess in the site of implanted regulator. In first patient 2 weeks after implantation and in second patient 2 months after implantation. One patient developed rejection of the regulator with aseptic abscess 18 months after implantation. After procedure was modified with placement of the regulator under the fascia 2/220 (0.9%) infections occurred. One patient developed an abscess 1 month after implantation. One patient developed abscess after I&D of Pilonidal cyst 6 months after Remeex sling procedure. Most likely due to hematogenious spread. No urethral obstruction has been produced.

Conclusions:
Remeex procedure is safe and highly effective in primary as well as recurrent cases of SUI and even in patients with narrow therapeutic margin without postoperative obstruction. Ability of Remeex TRT system for readjustment of sling tension long after the surgery allows helping patients with previously called "unsalvageable urethra". Modified sub-fascial TRT-Remeex placement allowed significant reduction of the device infection/ rejection rate.

Presentation Number: 165

A RANDOMIZED CONTROLLED TRIAL ON THE VALUE OF PREOPERATIVE URODYNAMIC INVESTIGATION IN WOMEN WITH STRESS INCONTINENCE.

S. A. VAN LEIJSEN[1], K. B. KLUIVERS[1], B. W. MOL[2], S. R. BROEKHUIS[1], A. L. MILANI[3], M. Y. BONGERS[4], C. I. AALDERS[5], V. DIETZ[6], C. H. VAN DER VAART[7], G. G. MALMBERG[8], J. P. HEESAKKERS[1], M. E. VIERHOUT[1];
[1]Radboud Univ. Nijmegen Med. Ctr., Nijmegen, Netherlands, [2]Academic Med. Ctr., Amsterdam, Netherlands, [3]Reinier de Graaf Groep, Delft, Netherlands, [4]Maxima Med. Ctr., Veldhoven, Netherlands, [5]Rijnstate Hosp., Arnhem, Netherlands, [6]Catharina Hosp., Eindhoven, Netherlands, [7]Alant Vrouw, Bilthoven, Netherlands, [8]Slingeland, Doetinchem, Netherlands.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: No

Objective:
The objective of this study was to compare, two test-treatment strategies in women with stress urinary incontinence (SUI). The first based on urodynamics and the second based on history, voiding diary and clinical examination.

Background:
In women undergoing surgical treatment for SUI, urodynamics may confirm or alter the clinical diagnosis or may influence the choice of intervention. The correlation between classification based on clinical evaluation and based on urodynamics is known to be poor. Until now, it remains unclear what the additional value of urodynamics is in improvement of success rates and in avoiding complications in individual cases. We evaluated whether the omission of urodynamics is non-inferior to enclosing urodynamics in the preoperative workup.

Methods:
We performed a multicenter randomized controlled trial. Women were eligible for the study in case they had SUI symptoms, for which physiotherapy had failed and were opting and candidates for surgical treatment. Incontinence had to be demonstrated on physical examination and/or voiding diary. Patients were excluded in case of previous incontinence surgery, a pelvic organ prolapse 1 centimeter beyond the level of the hymen and/or in case of residual bladder volume of more than 150 ml. Randomization occurred computer-generated and stratification was applied per centre.

Women with (predominant) SUI were randomly allocated to standard workup including urodynamics or to management based on history, clinical examination and voiding diary. At study entry several items were recorded, including symptoms, clinical examination, 48 h-bladder diary and validated quality of life questionnaires (Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ)).

Subscale scores of the UDI were transformed in a continuous scale ranging from 0 to 100. Success of treatment was evaluated at 6 weeks, 6, 12 and 24 months after the onset of treatment by a clinical examination, a voiding diary and completion of questionnaires (UDI, IIQ). The study was analysed according intention to treat.

The primary outcome of this study was the UDI score at 12 months after the onset of treatment. The power calculation was performed using the non-inferiority assumption. In each group 130 women would be needed to reach a power of 70% using less than 5% difference between patients with or without urodynamics in the preoperative workup.

Results:
In this RCT 59 women with SUI were included. The inclusion had to be stopped before accomplishment of the calculated sample size because of a hesitating inclusion rate. Twenty-eight patients were allocated to undergo treatment based on a workup without urodynamics and 31 women to a workup including urodynamics. Follow-up information was available for 97% of the included patients. Mean follow-up duration was 22 months (SD±7).

Table 1 shows the subjective and objective outcome according to the different definitions of cure. The mean improvement in score on the subscale urinary incontinence showed no difference between the groups after one year. The group without urodynamics was more likely to receive surgical management primarily, compared to those who underwent urodynamics (27/28 versus 26/31; RR 5.19 95% CI 0.57-47.50). The total subjective cure rate of urinary incontinence (subscale score 0) was higher in the group without urodynamics (RR 2.44 95% CI 0.79–7.51).

In the group with urodynamics, detrusor overactivity (DO) was the only urodynamic finding with direct therapeutic consequences. In three of the four patients in which DO had been found, this has led to abandoning of primary surgery. Omission of urodynamics did not result in a higher occurrence of de novo overactive bladder complaints (RR 0.18 95% CI 0.02–1.70). Voiding dysfunction after treatment occurred more in the group without urodynamics (7/28 versus 2/28; RR 5.19 95% CI 0.57–47.5).

Conclusions:
The addition of urodynamics did not change the outcome of treatment in women with predominant SUI. Cure rates are high and comparable to literature. Omission of urodynamics resulted in a higher rate of surgical interventions and higher subjective cure rates. Unfortunately, the inclusion proved to be difficult which limits the strength of our findings.

Table 1. Subjective and objective outcome according to the different definitions of cure.

			Group without urodynamics		**Group with urodynamics**	**Relative Risk**
Subjective outcome		N	*N*=28	N	*N*=31	[95% CI]
Global Improvement	Improvement	28	27 (96%)	29	27 (93%)	
	Equal	0	1 (3%)			
	Impairment	1 (4%)	1 (3%)			
Subjective cure (UDI)		28	21 (75%)	29	16 (52%)	2.44 [0.79–7.51]
Voiding diary*: no leakage reported		27	24 (89%)	26	21 (81%)	4.33 [0.81–23.10]

Objective cure					
Stresstest negative	25	23 (92%)	26	24 (92%)	1.28 [0.27–6.36]
Total cure					
Subjective and objective cured	25	18 (72%)	24	14 (58%)	1.84 [0.56–6.05]
Only objective cured		5 (20%)		8 (33%)	
Only subjective cured		0		1 (4%)	
No cure		2 (8%)		1 (4%)	

Footnote

Total subjective cure: score of 0 on the UDI subscale urinary incontinence and no leakage on voiding diary. Total objective cure: a negative stresstest by clinical examination. Total cure: combination of total subjective and total objective cure.

**= 48 h*

Presentation Number: 166

STRESS URINARY INCONTINENCE AFTER ROBOTIC SACROCOLPOPEXY WITH AND WITHOUT CONCOMITANT MIDURETHRAL SLING

A. K. CRANE[1], E. J. GELLER[1], A. P. WOODWARD[2], C. A. MATTHEWS[1];

[1]The Univ. of North Carolina at Chapel Hill, Chapel Hill, NC, [2]Virginia Commonwealth Univ., Richmond, VA.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

To determine the rates of de novo and persistent stress urinary incontinence (SUI) in women who underwent robotic sacrocolpopexy (RSCP) with or without midurethral mesh sling at two different surgical centers.

Background:

The lifetime risk of a woman undergoing surgery for prolapse or urinary incontinence ranges from 11.1% in the United States to 19% in Australia[1]. Furthermore, up to 30% of women require more than one surgery for recurrent prolapse or incontinence[2]. The ideal method to repair pelvic organ prolapse while also addressing recognized and "occult" incontinence is a subject of debate. With the advent of robotic technology, RSCP has become an alternative to abdominal sacrocolpopexy, with less blood loss, a shorter hospital stay and similar apical support[3]. To date, there are no published data on rates of persistent or de novo SUI in women undergoing RSCP.

Methods:

We performed a retrospective cohort study of women who underwent RSCP with (Group 1) or without (Group 2) concomitant midurethral sling between 2007 and 2010. Sling placement was based on the presence of urodynamic stress incontinence (USI). All subjects completed the Urinary Distress Inventory Short-form (UDI-6) questionnaire preoperatively and at 3 or 6 months postoperatively. The primary outcome measure was the subjective report of SUI at 3–6 months after surgery. Secondary outcomes included the subjective report of overactive bladder (OAB) symptoms, urinary frequency and urge urinary incontinence at 3–6 months after surgery. Results were analyzed using Student's *t*-test, Pearson chi-square and Fisher's Exact test.

Results:

A total of 82 women were included, 49 from site A and 33 from site B. The overall rate of postoperative SUI was 31.7%, and 30.8% of these had a concomitant sling. There were no differences in baseline demographics between the two groups. Overall, the rate of postoperative SUI was lower in women who underwent RSCP with concomitant sling compared to those who underwent RSCP alone (18.6% vs. 46.2%, $p=0.007$). Furthermore, severe SUI was less common in the group that had a concomitant sling (2.4% vs 15.8%, $p=0.049$). The number of slings needed to prevent one case of de novo SUI was 3.6. There were no differences between the two groups for OAB symptoms (39.5% vs. 50%, $p=0.470$), urinary frequency (27.9% vs. 30.8%, $p=0.776$) or urge urinary incontinence (25.6% vs. 34.2%, $p=0.396$). Preoperative OAB was not predictive of persistent or de novo postoperative OAB (42.2% vs 45.5%, $p=0.776$).

Conclusions:

Women who undergo RSCP alone report a high rate of de novo SUI, which is also more likely to be severe. Concomitant sling placement significantly reduced this risk. Overactive bladder was common in both groups, with no difference based on sling placement. We recommend considering the placement of a concomitant midurethral sling at the time of RSCP.

References (optional):

1. *Obstet Gynecol*. Nov 2010;116(5):1096–100.
2. *Obstet Gynecol*. Apr 1997;89(4): 501–506.
3. *Obstet Gynecol.* Dec 2008; 112(6):1201–6.

Presentation Number: 167

PROSPECTIVE EVALUATION OF THE AJUST SINGLE INCISION TRANSOBTURATOR SLING PROCEDURE FOR STRESS URINARY INCONTINENCE IN WOMEN: RESULTS OVER ONE YEAR FOLLOW-UP

J. CORNU[1], P. SÈBE[1], L. PEYRAT[1], C. CIOFU[1], V. R. LUCENTE[2], F. HAAB[1];

[1]Tenon Hosp., PARIS, France, [2]The Inst. for Female Pelvic Med. & St. Luke's Hosp., Allentown, PA.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

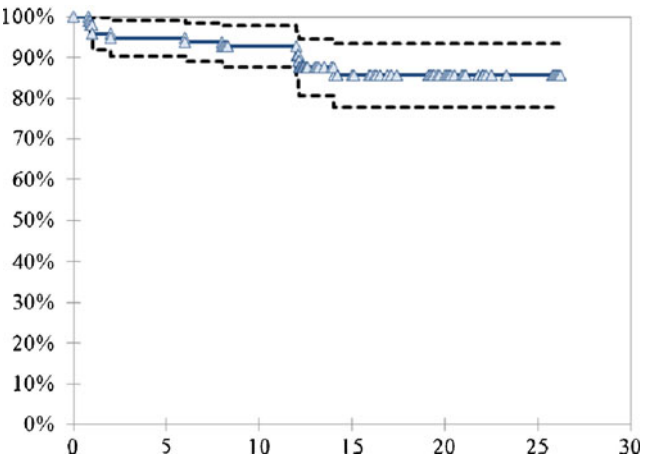
Objective:
To prospectively assess the efficacy of Ajus, a new minimally-invasive, single-incision transobturator sling procedure for women with stress urinary incontinence (SUI) with a minimum follow-up of one year.

Background:
From November 2008 to February 2010, patients with SUI or mixed urinary incontinence with predominant SUI were implanted with the Ajust sling in one center. Age, medical history, clinical examination with cough test, TVT and Bonney tests, urodynamics were assessed preoperatively. The protocol was reviewed by the local independent ethics committee, and all patients gave written informed consent. 97 consecutive patients (mean age 56.7±12 [35–87]) were included in this prospective evaluation. 36/97 patients had preoperative overactive bladder (OAB) symptoms managed by anticholinergics. No patient had associated pelvic organ prolapse. All had urethral hypermobility and had positive stress test at clinical examination. Twelve patients had maximal urethral closure pressure (MUCP) inferior than 30 cm H_20.

Methods:
All patients were implanted with an Ajust adjustable single incision sling (Bard Urological Division, Covington, GA, USA). 94 patients were managed on an outpatient basis (local anesthesia), and three patients were hospitalized for 24 h (general anesthesia). The following efficacy parameters were assessed 1, 6, 12 months and then yearly after surgery: pad usage, clinical examination including a stress test to evaluate SUI, validated patient global impression of improvement (PGI-I) scale, bladder diary, and adverse events. The primary endpoint was focused on efficacy based on the following definition: patients were classified as cured for SUI when wearing no pads, having no stress-related leakage and presenting a PGI-I score of one or two, and as failure otherwise. Durability of the results was assessed through a Kaplan-Meier analysis.

Results:
Mean operating time was 14,9 min±0,6 [10–15]. Blood loss was minimal for all patients. Fifty percent of patients having undergone only the sling procedure did not take any oral medication at home after surgery, and other only used acetaminophen. One patient developed a postoperative vaginal bleeding that was managed surgically 8 h after surgery. One patient presented acute urinary retention after removal of her urinary catheter, necessitating 24 h of catheterization. No organ perforation or injury occurred.
Mean follow-up was 16±5 months [12–26] . Data showed that 85/97 patients (86%) used no pads, were fully satisfied of the procedure (one or two on PGI-I scale), and had no leakage at last follow-up. These results were durable as shown in Fig. 1 representing the rate of patients cured during follow-up (months). Pad usage was significantly reduced ($p<$ 0.0001). Five patients presented with de novo urgency, and did respond to trospium chloride treatment. One patient died one year after the procedure, from a cervical cancer, not known at the time of surgery. One case of lateral erosion the sling was noted at 6 months follow-up. Two patients experienced mild pelvic pain during three months that spontaneously resolved. One patients had mild sensation of dysuria at last follow-up (with normal outflow), and three patients had urinary tract infection treated by antibiotics.

Conclusions:
Our initial experience using the Ajust single incision sling system for SUI in women shows that this new technique is safe, time efficient, reproducible and associated with limited adverse events. It is easily performed in an outpatient basis and therefore should be cost effective. As a first line treatment, durable results are obtained one year after surgery with a success rate of 85%. These results are in favor of a real clinical advantage of this new device, but have to be confirmed in large, controlled and comparative studies with longer follow-up.



Presentation Number: 168

RETROSPECTIVE STUDY OF PATIENTS WHO UNDERWENT TENSION FREE VAGINAL TAPE - A 5-YEAR REVIEW

S. NARANG, H. C. HAN, L. C. LEE, A. TSENG, H. F. WONG; KK Women's & Children's Hosp., Singapore, Singapore.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
The current study aims to evaluate the cumulative experience of TVT (Tension free Vaginal Tape) procedure for female stress incontinence at a specialized urogynaecology centre. This study evaluates the efficacy, safety and long term complications over a period of 5 years after the tape procedure.

Background:
Stress urinary incontinence is an important health concern in women, and significantly affects their quality of life. Previously, open abdominal procedures like Burch colposuspension was the main operation with significant long term success; however it was also associated with surgical morbidity and prolonged hospital stay. Emergence of midurethral tapes like the TVT has revolutionized the management of female stress incontinence and may prove to be a landmark for urogynaecology in this era of minimally invasive surgery. The present study aims to evaluate the efficacy and safety of TVT procedure over a period of 5 years, performed at a specialized centre under the supervision of a single experienced surgeon.

Methods:
This is a retrospective, observational study done at a specialized urogynaecology centre. All women who underwent TVT from 1998 to 2004 were included in this study. The case records were reviewed and details such as demographic profile, preoperative symptoms, clinical evaluation, erect stress test and urodynamic study were recorded. Operative details included operating time, concomitant surgery and blood loss. Complications included bladder perforation. Post operative details included recovery, fever, prolonged catheterisation, duration of hospital stay and readmission.

Postoperative review was done at 6 months, 1 year, and followed by yearly for 5 years. A urodynamic study was repeated at 6 months for objective evaluation. The patients were also evaluated for long term voiding dysfunction, tape erosion and recurrent urinary tract infections. Patients who defaulted were recalled by telephone, and those who were unable to come back to the hospital for follow-up were interviewed on the phone using a standard set of questions. The dataset was analysed using SPSS software, and the results were compared over 5 years.

Results:
There were a total of 827 patients who underwent TVT procedure from 1998 to 2004. The mean age was 54.9±25.57. 54.5% of patients were postmenopausal.

Pure stress incontinence symptoms was present in 62.6% cases, while mixed stress and urge incontinence symptoms was present in 37.4% cases. 57.4% patients were operated under regional anesthesia whereas 11.7% were operated under local anesthesia. 61.3% patients had demonstrable leakage on erect stress test, with mean amount of leak of 15.52±33.49 g. Preexisting detrusor overactivity on UDS was found in 27 patients (3.3%).

Intraoperative bladder perforation was noted in 4.1% cases and blood loss of ≥200 ml was noted in 4.6% cases of TVT with no other concomitant surgery. Post-operative fever of >37.5 ° was detected in 8.9% cases, and all the cases responded to change of antibiotics.

Post operative voiding difficulty in the form of slow flow or incomplete bladder emptying was reported by 9.2% patients at 6 months, and only 2.3% patients at 5 years. 10 patients (1.2%) required prolonged catheterisation of more than 7 days due to persistent high residual urine (>150 mls). 13 patients (1.6%) required loosening or cutting of the tape. Tape erosion was noted in 8(1.3%) patients at the end of 6 months, and only 2 patients at the end of 5 years (0.4%). Overall 98.5% patients were satisfied with the TVT surgery, under which 89.1% were completely cured and 9.4% had improved leakage. The cure rate was 91.1% at 1 year and 73.3% at 5 years.

Conclusion:
TVT as compared to other more extensive surgical procedures is a fairly simple technique for female stress incontinence, as approximately 11.7% patients could be operated upon under local anesthesia with a short hospital stay. The long term cure rate at the end of 6 months, 1 year and 5 years was found to be 89.1%, 91.1% and 73.3% respectively. Additionally, 9.4%, 8.0% and 17.9% patients showed improvement in terms of leakage at 6 months, 1 year and 5 years—with an overall patient satisfaction rate of >95%.

The risk of complications reduces with increased cumulative experience and an improved learning curve. At the end of 5 years, 93.8% patients were doing well with no long term complications. However, the relatively high defaulter rate at 5 years (27.1%) may be one of the key limiting factors.

There are currently 112 more patients being recalled and awaiting review/follow-up as we speak. Additional information from there may then improve the dataset and also validate the study results in a better way. Based on the current available data however, TVT can be considered as a safe and effective minimally invasive surgical alternative for female stress incontinence.

Reference:
1) (2001). *International Urogynecol J*, 2: 24–27

Presentation Number: 169

PROPRIOCEPTION AND AWARENESS TRAINING PRIOR PELVIC FLOOR MUSCLE EXERCISES FOR TREATMENT OF URINARY INCONTINENCE: RANDOMIZED CONTROLLED TRIAL

L. STÜPP, D. YAMAMOTO, T. FONSECA, A. M. RESENDE, **C. PLOGER**, E. OLIVEIRA, R. A. CASTRO, M. J. GIRÃO, M. G. SARTORI;
Federal Univ. of Sao Paulo, São Paulo, Brazil.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To evaluate the effectiveness of proprioception and awareness training (PAT) prior pelvic floor muscle training (PFMT) for treatment of urinary incontinence (UI).

Background:

PFMT should be recommended as a first-line conservative management program for stress UI(1). Women with UI may demonstrate a very weak PFM contraction, and a lack of proprioception and awareness of these muscles. Useful techniques in this case would be those that facilitate a contraction (2, 3).

Methods:

Women with previously untreated stress or mixed UI, were asked to participate in the trial. Consenting women were randomized to receive home PFMT alone or in combination with three sessions of PAT. The outcomes of interest were PFM function, activation, symptoms of urinary loss and the impact on quality of life.

At the first appointment, a standardized history was taken, and PFM assessment was carried out. The evaluation included: (a) evaluation of PFM function, considered strength and endurance. To evaluation of muscle strength was used the Oxford Scale. Endurance was registered as the length of time, up to 10 s, that a maximal voluntary contraction (MVC) could be sustained. (b) surface electromyography (sEMG) evaluation of pelvic floor performed by vaginal probe. Symptoms of urinary loss were registered by a routine questionnaire of physiotherapy ambulatory. The impact on quality of life was measured by King's Health Questionnaire.

A 12-weeks standardized PFMT program was given to both groups and women were encouraged to perform three sets of exercises daily (one set consisted of eight maximum voluntary contractions held for 6 s, with 12 s rest between each contraction, followed by three fast contractions in a row). The control group received the protocol only by verbal command of physiotherapist. Women of PAT group participated of three sessions to achieve sensory awareness of the PFM prior PFMT. At the first appointment, instruction was given concerning anatomy and function of the PFM. The training began with diaphragmatic breathing with voluntary PFM contraction, visualized in the mirror in many positions. At the second appointment, was performed a proprioceptive technique with a vaginal cone and quick reflex. The third session consisted of intensive contraction training of the PFM during an increase in abdominal pressure, termed *the Knack maneuver*. In addition, patients learned to contract the PFM while coughing and other activities.

Results:

There were no significant differences between groups with respect to age (p=0.457), parity (p=0.665), body mass index (p=0.237) and hormonal status (p=0.994) at baseline. The PAT group obtained significantly increase of PFM function and activation after treatment (Table 1).

Table 1 - PFM function and activation of two analyzed groups

Variable	Group	Mean	SD	P*
Oxford [a]	PAT	2.4	0.8	0.189
	Control	2.0	0.8	
Oxford [b]	PAT	3.6	0.7	<0.001
	Control	2.1	0.8	
Endurance [a]	PAT	3.2	1.6	0.987
	Control	2.9	1.1	
Endurance [b]	PAT	7.4	1.8	<0.001
	Control	3.0	1.4	
MVC [a]	PAT	10.4	3.0	0.927
	Control	10.7	4.8	
MVC [b]	PAT	15.4	4.2	0.008
	Control	11.0	4.3	

[a] Baseline [b] After treatment MVC - Maximal Voluntary Contraction

* Wilcoxon test

With respect to symptoms of urinary loss, PAT group presented better improvement than control group in cough, sneeze, squat and weight lifting. This group also had significant improvement on quality of life (Table 2 and 3).

Table 2 - Changes observed in symptoms of urinary loss after treatment.

Symptoms	**N [Freq.(%)]**			
	PAT		**Control**	
Baseline (n=22)	Final	(n=21)	Baseline (n=22)	Final (n=21)
Cough	18 (85.7)	6 (28.5)	17 (80.9)	14 (66.6)
Sneeze	18 (85.7)	7 (33.3)	17 (80.9)	13 (61.9)
Squat	12 (57.1)	4 (19)	10 (47.6)	11(52.4)
Weight lifting	13 (61.9)	3 (14.3)	11 (52.4)	11 (52.4)

Table 3. Impact on quality of life of both studied groups after treatment.

Domains	**PAD (n=22)**	**Control (n=19)**
	P value*	P value*
General Health	0.006	0.310
Incontinence impact	<0.01	0.783
Physical activities limitation	0.003	0.832
Physical limitations	<0.01	0.157
Social limitations	0.001	0.750
Personal relationships	0.066	0.317
Emotions	0.131	0.715
Sleep/dispositions	0.343	0.180
Gravity	<0.01	0.99

Conclusions:

PAT is effective on improvement of PFM function, activation, symptoms and quality of life and should be recommended prior PFMT.

References:

1.Hay-Smith EJC, Dumoulin C (2006) Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. The Cochrane Data Base of Systematic Reviews, 1st issue. The Cochrane collaboration. UK, wiley&sons, LTD.

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3.Brown C 2001. Pelvic floor re-education: a practical approach. In: Corcos J, Schick E (eds). The urinary sphincter. Marcel Decker, New York, p 459–473.

Presentation Number: 170

PREVALENCE OF URINARY INCONTINENCE IN PORTUGUESE FEMALE ATHLETES

T. H. DA ROZA[1], T. MASCARENHAS[2], J. A. SANTOS[3], R. GARGANTA[3], R. NATAL JORGE[1], M. P. DE ARAUJO[4];
[1]IDMEC - Pólo FEUP, Porto, Portugal, [2]Faculdade de Med. da Univ.e do Porto - Hosp. São João, Porto, Portugal, [3]Faculdade de Desporto da Univ.e do Porto, Porto, Portugal, [4]UNIFESP, São Paulo, Brazil.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aims of the present study are (1) to determine the prevalence of UI in female athletes in Portugal; (2) to describe the types and severity of incontinence; (3) analyze the prevalence of IU between sports, and (4) to assess the impact of UI in quality of life (QoL).

Background:

Urinary incontinence (UI) is the most common dysfunction of the Pelvic Floor (PF), being a major contributor to the physical and psychological morbidity of women. The International Continence Society (ICS) defines UI as "the complaint of any involuntary leakage of urine" [1]. Among the types of UI the stress incontinence (SUI) is one of the more common forms, the other two are the mixed incontinence and the urge urinary incontinence (UUI).

SUI is characterized by urinary loss when intravesical pressure exceeds maximum urethral pressure in the absence of detrusor muscle contraction. It is common in cases of cough, sneeze, or in exercise. UUI is the complaint of involuntary leakage accompanied by or immediately preceded by urgency [1]. Although the prevalence rates of UI vary according to the target population, is estimated that 8-58% of the overall adult female have symptoms of incontinence [2].

The analysis of incontinence in young nulliparous women indicates a high prevalence of UI in athletes, especially those who practice high-impact sports (Trampoline found 80% loss) [3]. There are multiple risk factors to be associated with SUI. These include age, vaginal delivery, obesity, exercise and inherently weak connective tissue and pelvic floor muscles; UUI, however, is often idiopathic.

There is no data about overall prevalence of UI in female athletes from Portugal. However, it is important to determine the distribution of the UI in sports, that there may be a concern to prevent dysfunction of PF dysfunction.

Methods:

This cross-sectional study was conducted among female athletes in Portugal. All subjects signed the consent form approved by Ethics Committee at the São João Hospital, Porto, Portugal. The study was conducted between July 2010 and November 2010.

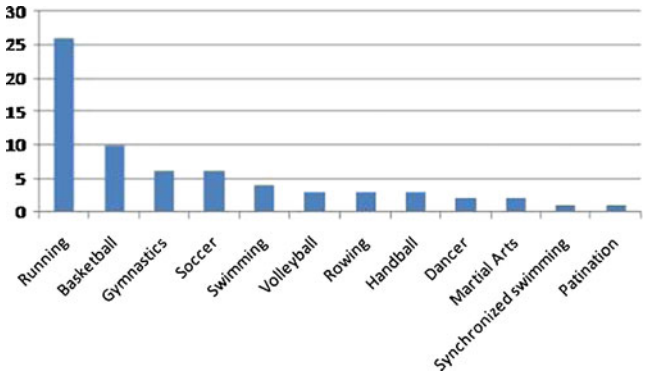
The sample consisted of 230 female athlete with mean age of 19.3 (range 15–40) years and body mass index (BMI) 21.4 (range 16.7-27.3) Kg/cm2. The participants answered to a questionnaire that consisted of two parts.

The first part was designed to investigate women's characteristics: age, marital status, education status, number of pregnancy, height and weight, regular menstrual cycle, hormonal contraception, and the type of sport that they practice.

For the second part, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was applied. This consisted of three items; the first was designed to determine the frequency, the next analyzes the severity of UI, and the last item is related with its impact on women's QoL. With the sum of these three questions we get the total ICIQ-SF score (between 0 and 21). The last question is related to the type of loss: when the athlete has eight items of choice and can choose more than one answer.

Results:

The overall prevalence of UI was 29.1%. The most common type of IU found was SUI with 58.2%, following by UUI (28.9%) and mixed urinary incontinence (12.9%). Graph 1 shows that Running was the sport more common to occur urinary leak and swimming, rowing and patination was minor frequent.



Graph 1: Prevalence of IU distributed by the different sports.

The influence of UI symptoms on the perception of QoL varied according to the severity of symptoms, 8.70% of athletes reported that the loss of urine did not interfere with the quality of life, while 15.65% considered a mild, 3.48% a moderate and 1.30% severe or great extent.

Conclusions:

The presented results demonstrate that the prevalence of UI in female athletes in Portugal is 29.1%. High-impact sports are those which have the highest prevalence, when compared with low-impact, and 20.43% of athletes reported the urinary leakage to be a problem.

References:

[1] Urology. 2003.
[2] Qual Life Res. 2005.
[3] Scand J Med Sci Sports 2002.

Presentation Number: 171

GLOBAL POSTURAL REEDUCATION AND PELVIC FLOOR MUSCLES TRAINING, COMPARATIVE STUDY FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE - TWO YEARS FOLLOW UP

C. FOZZATTI, V. HERRMANN, C. RICCETTO, P. PALMA; UNICAMP, Campinas, Brazil.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

To evaluate the results of Global Postural Reeducation (GPR) and Pelvic Floor Muscles Training (PFMT) for the treatment of female Stress Urinary Incontinence (SUI), two years after the end of treatment.

Background:

Prospective**,** comparative and controlled cohort study with convenience sample. Fifty-two patients with SUI were selected. The first 26 underwent a GPR treatment (G1) and the next 26, a PFMT (G2). Twenty-five patients from G1 and 17 from G2 concluded the treatment. The patients that had improvement or were cured at the end of the treatment were evaluated after 2 years.

Methods:

The evaluation was subjective evaluation, *King's Health Questionnaire (QoL)*, 3-day voiding diary and Functional Evaluation of Pelvic Floor (FEPF).

G1 was treated with GPR, with individual weekly sessions. Patients performed stretching postures, individually defined after postural evaluation and were not requested to perform exercises at home.

G2 was submitted to the PFMT treatment. The exercises were performed 4 days a week, been one time under individual supervision and patients were requested to continue the exercises at home after the end of the treatment.

Results:

The groups were homogeneous on age, weight, sympton duration, height, number of pregnancies, vaginal deliveries and caesarian.

The subjective evaluation of G1 had shown, at the end of the treatment, that 19% of women were cured. This number increased to 47.6% after 2 years. In G2, 100% reported improvement and after 2 years this number was 16.7% of cure and 33.3% of worsening.

There was a significant decrease in the leakage episodes for both groups ($p<0.0001$), without significant difference between them ($p=0.0787$). The improvement was kept after 2 years. In G1, 33.3% of women did not present leakage at the end of the treatment and this proportion increased to 62.8% after 2 years. In G2, 8.3% did not present leakage at the end of the treatment and 16.7% after 2 years.

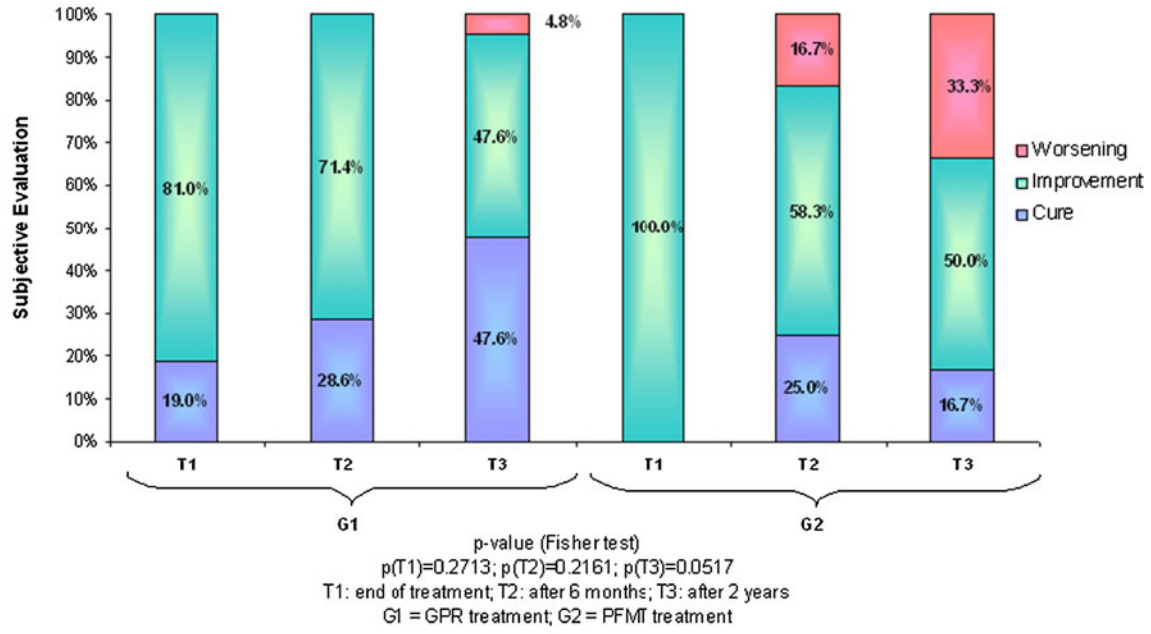
Pad use had a significant decrease in both groups ($p=0.0001$), without significant difference between them ($p=0.0579$). At the end of the treatment 82% of G1 did not use pad and this proportion was kept after 2 years. In G2, 70% did not use pad at the end of the treatment however, after 2 years this number decreased to 40%.

FEPF improved progressively in G1 throughout the evaluation times, while in G2 it presented significant improvement at the end of the treatment and kept this result after 2 years ($p=0.045$). There wasn't significant difference between the groups (T1: $p=0.1518$; T2: $p=0.4395$; T3: $p=0.2658$).

The analysis of the *QoL* demonstrated significant improvement in all domains in both groups in all evaluation times. G1 presented significant improvement over G2 in the following domains: General Perception of Health (p=0.027), Personal Relations (p=0.013) and Emotions (p=0.0055).

Conclusion:

GPR had shown to be an effective alternative for the treatment of female SUI, showing results that were comparable to the PFMT at the end of the treatment and after 2 years.



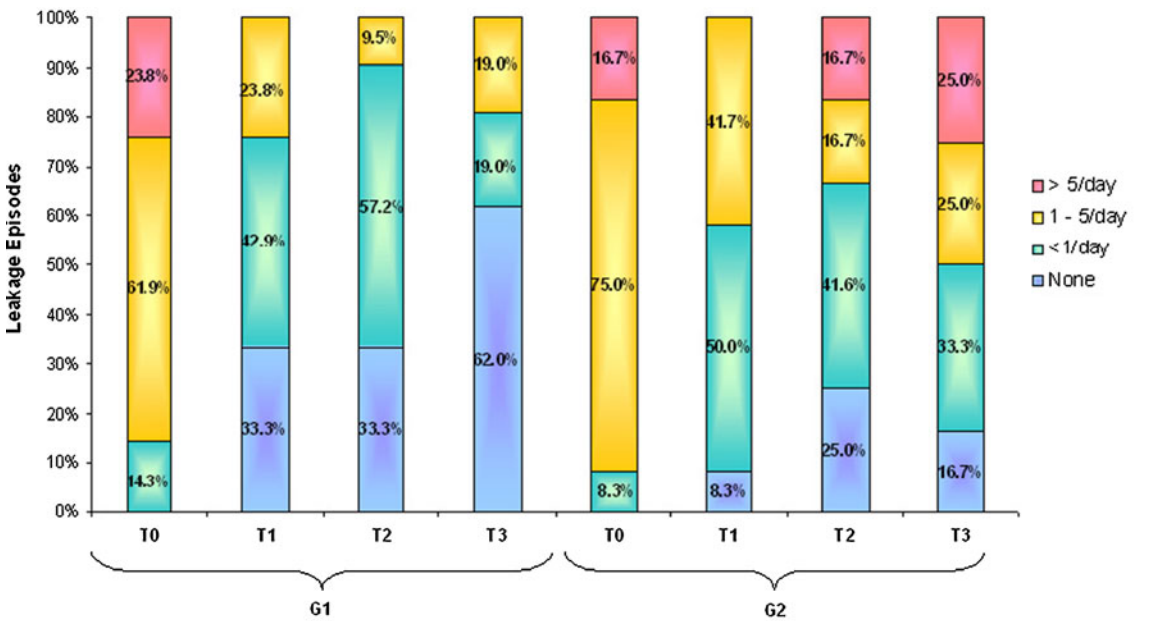
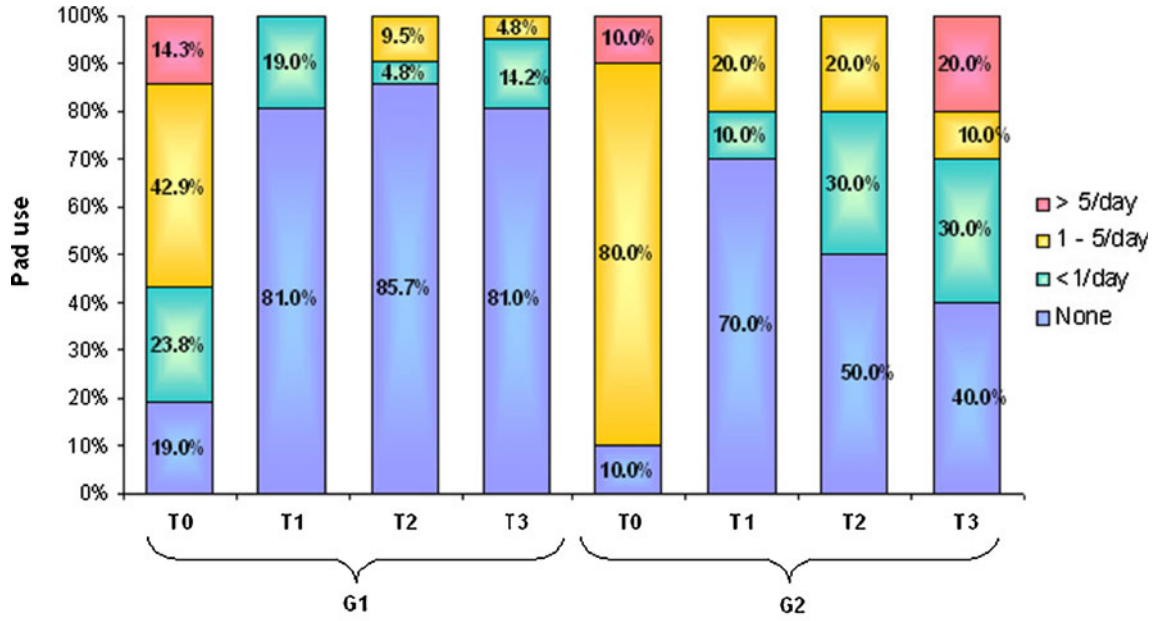
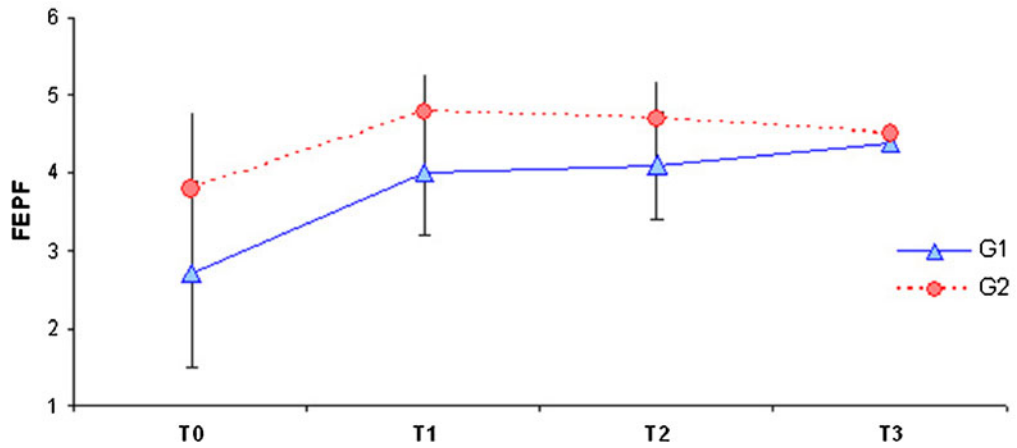


Fig. 1. Subjective evaluation and number of leakage episodes



Effect	p-value EEG
time	= 0.0001 (T0 and T1; T0 and T2; T0 and T3)
group	0.0579

T0: before treatment; T1: end of treatment; T2: after 6 months; T3: after 2 years
G1 – GPR treatment; G2 – PFMT treatment



Effect	p-value (ANOVA for repeated samples)
Groups	0.6993
Time	0.9944
Time*Group	0.0045

T0: before treatment; T1: end of treatment; T2: after 6 months; T3: after 2 years
G1 = GPR treatment; G2 = PFMT treatment

Fig. 2. Pad use and FEPF

Presentation Number: 172

THE MINIARC SINGLE INCISION SLING FOR FEMALE STRESS URINARY INCONTINENCE: CLINICAL RESULTS OF A PROSPECTIVE EVALUATION WITH A MINIMUM FOLLOW UP OF ONE YEAR.

C. R. HOGEWONING, I. RUHE, M. D. BEKKER, C. J. HOGEWONING, H. PUTTER, M. C. DERUITER, R. C. PELGER, H. W. ELZEVIER;
Leiden Univ., Leiden, Netherlands.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The objective of this study was the assessment of the efficiency of the MiniArc and the effects on the quality of life and overall functioning post-surgery.

Background:
Not much is known about the efficiency of stress urinary incontinence curing surgery using the MiniArc single incision sling. Furthermore no studies describe the impact on quality of life and everyday functioning of this procedure.

Methods:
Ninety-two patients were operated from March 2008 to November 2009 in a teaching Hospital, and evaluated in this study. The 6 weeks and 1-year post-operative data are presented. All patients suffered from predominant stress urinary incontinence. After 1 year the response was 74%.

The evaluation was performed using a questionnaire consisting of the EuroQol-5 Dimensions (EQ-5D), the Patient Global Impression of Improvement (PGI-I), the Incontinence Impact Questionnaire (IIQ), the Urinary Distress Inventory (UDI), the Prolapse/Urinary Incontinence Sexual Questionnaire, short form (PIS-Q) and the Defecation Distress Inventory (DDI).

Results of both pre- and post operative questionnaires were scored and for the UDI, IIQ and DDI converted in a scale ranging from 0 to 100 (higher = negative). Statistics were performed in SPSS release 17 (SPSS Inc., Chicago, IL, USA). P-values<0.05 were considered statistically significant. For multiple comparisons a Bonferroni correction was conducted after the paired sample T-test.

Results:
Six weeks after surgery 84% of the patients stated to be completely relieved of their incontinence and had an improved EQ-5D together with reduced overall complaints (significant). At the 1-year evaluation success rates dropped to 44%. Still, 86% of the patients stated improvement 1 year after surgery, which was further confirmed by persisting significant improvements in everyday functioning. Limitations of this study were the single center setting and the lack of objective measurements.

Conclusions:
Despite promising results after 6 weeks, the 1-year follow-up suggests that the MiniArc is less effective in the treatment of stress urinary incontinence than the TVT. However, the improvement rate of 86% after 1 year is promising. More studies will be needed to further support these results.

Presentation Number: 173

OPEN COLPOSUSPENSION AFTER FAILED MIDURETHRAL TAPE

I. GIARENIS, **H. MASTOROUDES**, L. CARDOZO, D. ROBINSON;
King's Coll. Hosp., London, United Kingdom.

Consent obtained from patients: No
Level of support: Not Applicable
Work supported by industry: No

Objective:
To evaluate the outcome of open colposuspension for women with urodynamic stress incontinence who had previously undergone a failed midurethral tape procedure.

Background:
Midurethral tapes have become the 'gold standard' for surgical management of stress urinary incontinence (SUI) [(1)]. However, a small proportion of treated patients experience surgical failure [(2)]. The management of persistent or recurrent SUI after failed midurethral tape presents a new challenge as there is no consensus regarding the treatment of these complicated cases [(3)]. The options that have been reported in the literature in small cohort studies are bulking agents, shortening of the preimplanted tape, repeat midurethral tape, adjustable slings, spiral slings and placement of an artificial urinary sphincter. To date, little is known about the outcome of open colposuspension in this group of patients.

Methods:
This was a retrospective study in a tertiary referral urogynaecology unit. We included all women who underwent open colposuspension after failed midurethral tape between June 2005 and June 2010. Data were collected from the patient's records using a standardised proforma. Pre-operative assessment included completion of a bladder diary and a validated symptom and disease-specific quality of life questionnaire (Kings Health Questionnaire). Uroflowmetry, video-cystourethrography, pressure-flow studies and urethral pressure profilometry were performed prior to surgery.

The operations were performed by the senior authors. The paravaginal tissues were sutured to the ipsilateral ileopectineal ligament on each side with four number one polydioxanone sutures. A suprapubic catheter was inserted at the end of the procedure and left on free drainage until the second post-operative day when clamping was commenced. When the residual urine was less than 100 ml and the woman was passing good volumes the catheter was removed and she was allowed home.

The patients were reviewed 6 weeks post-operatively in the outpatient clinic and had repeat urodynamic study 6 months following the surgery. Some patients had further follow-up based on their symptoms. Subjective cure rate was defined as

absence of any episodes of stress incontinence as reported by the patients at the time of follow-up. Objective cure rate was defined as the absence of urodynamic stress incontinence in the post-operative urodynamic study.

Results:

Thirteen women were included in our study with a mean age of 55 years (range 40–71) and mean BMI of 26 (range 19–35). Sixty-one percent of the women had a previous retropubic tape, 39% a previous transobturator tape and 23% had more than three incontinence procedures. Concurrent abdominal hysterectomy was performed in three women. The mean operative time was 77 min (range 43–123) including the time for the concomitant surgery, while the median length of hospitalisation was 3 days.

At a mean follow-up of 12 months subjective and objective cure rate were 85% and 77% respectively. There was only one woman who had severe urodynamic stress incontinence post-operatively who was treated with transurethral injection of bulking agents. A low maximum urethral closure pressure (less than 20 cm H2O) was not associated with treatment failure in our sample.

Twenty three percent of the women developed de novo detrusor overactivity that responded to antimuscarinic treatment. Long-term voiding difficulty was observed in only one patient, who performed clean intermittent self-catheterisation for 3 months. Posterior vaginal wall prolapse requiring pelvic floor repair was found in 23% of the women postoperatively.

Operative complications included one bladder injury and bilateral ureteral kinking in a woman who had multiple previous surgical interventions. This patient was treated with ureteral stenting for 6 months.

Conclusions:

Open colposuspension appears to be an effective option for the treatment of persistent or recurrent stress urinary incontinence after failed midurethral tape with a high success rate. Due to the associated morbidity, the need for individualised and realistic preoperative counselling is of paramount importance.

References:

1. *Int Urogynecol J* 2009; 20: 619–621
2. *Int Urogynecol J* 2008; 19: 1043–1047
3. *J Obstet Gynaecol Res* 2010; 36: 467–473

Presentation Number: 174

MONARC VERSUS MINIARC: RETROSPECTIVE STUDY

C. FATIMA, C. CONDE, J. MARTINEZ SAGARRA, C. MARINA, V. RODRIGUEZ TESEDO, A. RIVERO CARDENES, J. SANCHEZ, L. ALVAREZ BUITRAGO;
Hoaspital Rio Hortega, valladolid, Spain.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

Suburethral sling is a surgical treatment contrasted for stress urinary incontinence. The aim of this study is to evaluate the functional outcome Monarc versus MiniArc.

Methods:

We evaluate 310 women operated from Appril 2004 to December 2010 for stress urinary incontinence. 210 with Monarc and 100 with Miniarc. All women expressed informed consent. Data were treated with Chi2 test.

Results:

	Monarc	Miniarc	P
N	210	100	
Age	57,80±11,23	59,05±11,60	0,831
Children	2,4±1,46	2,19±1,4	0,091
Follow up	41,55±23	18,3±3,1	0,00
Hospital stay	3,8±2,42	2,46±1,19	
Early complication	0	0	1
Late complication	29%	39,6%	0.058
Surgical time	27,6±11,63	19,66±11,17	0,00
Success rate	79,5%	73,3%	0,188

	Monarc	miniarc
Erosion	6	Erosion: 7
Stress incontinence	9	Stress incontinence: 18
Urgency de novo	17	Urgency de novo: 9
Urgency maintained	20	Urgency maintained: 2
Urinary retention	4	Bladder perforation: 1
Urinary infection	1	Dysuria: 2
cystocele	5	Cystocele: 6
Surgical repair	5	Surgical repair: 9

Conclusions:

Miniarc technique is quicker, needs less hospital stay, but shows a less success rate and more complications. Erosion can be explained by transversal incision that it has been related with a higher rate of erosion. Also, a high recurrence rate could be expressed by the use of local anaesthesia which produce oedema, and difficult a good mesh anchor.

Presentation Number: 175

CHANGES IN QUALITY OF LIFE OF WOMEN WITH STRESS URINARY INCONTINENCE TWO YEARS AFTER FIRST DELIVERY

M. ARRUE, I. DIEZ-ITZA, L. IBAÑEZ, J. PAREDES, A. MURGIONDO;
Hosp. Donostia, San Sebastian, Spain.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

This study aimed to analyze the impact of postpartum stress urinary incontinence (SUI) in quality of life of primiparous women.

Background:
Lower urinary tract symptoms, namely SUI, often appear for the first time during pregnancy and after delivery. Childbearing also gives rise to physical and emotional consequences, which largely affect primiparous women. However, the impact of stress urinary incontinence on quality of life in postpartum women is nearly unknown. Some authors (1) described a worsening of quality of life of postpartum women that could be due to other causes of morbidity that were not linked to SUI.

Study design:
A longitudinal cohort study including primigravid women was undertaken to evaluate the impact on quality of life of SUI 2 years after delivery. Women were invited to participate when they came to give birth to our hospital, although the ones in active phase of labour that were affected by the pain of uterine contractions were initially excluded. We also considered the following exclusion criteria: Multiple pregnancies, gestational age less than 37 weeks, and previous urogynecological surgery or malformations.

Assessment of the impact of urinary symptoms on quality of life was evaluated with the Kings Health Questionnaire (KHQ). Data were collected at inclusion and 2 years after delivery. At inclusion women were prompted to complete the questionnaire considering their symptoms before pregnancy. The KHQ is a self-administrated and condition specific questionnaire that allows measuring the impact of urinary symptoms on quality of life. Spanish version of this questionnaire has been validated (2). This questionnaire is scored from "0": not at all to "100": a great deal. Statistical analyses were used for mean comparison (T-test paired).

Results:
We included 249 pregnant women who completed both pregestational and postpartum King's Health Questionnaire. Mean age was 31.2 years (range: 21–43) and mean BMI was 23.4 (range: 16.6-40.8). From the total, 148 (59.4%) women had a spontaneous vaginal delivery, 68 (27.3%) women delivered by instrumental vaginal delivery and 33 (13.3%) women had a cesarean section. Stress urinary incontinence was reported by 80 (32.12%) women 2 years after first delivery.

The results of the analysis of the impact of postpartum SUI on quality of life of primiparous women are shown in Table 1. We observed that 2 years after delivery women with SUI symptoms had an overall score of 10.2 in the KHQ, whereas the corresponding score before pregnancy was 3.1. The questions measuring general health and overall health related to urinary symptoms showed a higher score in postpartum period, indicating a clear worsening of quality of life after delivery. The worsening also included role limitations domain, physical limitations, social limitations and personal relationship domain besides of emotions and sleep domains. In summary, women with SUI had a lower quality of life 2 years after delivery in comparison with pregestational period.

Conclusions:
Women who suffer postpartum SUI had a worsening in their quality of life from pregestational period showed in all the domains of the KHQ questionnaire.

References:
1. Int Urogynecol J 2004; 15:160–164
2. Med Clin. 2000; 114:647–652.

Table 1. Comparison of pregestational and 2 years postpartum quality of live in women with stress urinary incontinence

Domain		Pregestational (n=80)	Postpartum (n=80)	p value
Overall score	mean, SD	3.1±3.5	10.2±8.3	0.000
General Health	mean, SD	15.6±12.1	22.8 ±14.4	0.000
Impact	mean, SD	3.9±14.5	15.7±21.1	0.000
Role	mean, SD	0.6±4.1	4.1±11.1	0.000
Physical	mean, SD	0.4±2.2	3.2±7.4	0.000
Social	mean, SD	0.0±0.0	1.7±7.3	0.037
Personal[a]	mean, SD	0.1±1.2	3.9±8.7	0.000
Emotions	mean, SD	1.2±5.1	7.3±13.7	0.001
Sleep	mean, SD	2.9±8.2	22.6±20.4	0.000

SD: standard deviation

[a] Missing data for one woman

Presentation Number: 176

AN OPEN STUDY OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR FEMALE STRESS URINARY INCONTINENCE IN SELECTED POPULATION OF WOMEN

K. DLOUHA, L. KROFTA, M. KRCMAR, J. FEYEREISL, M. OTCENASEK, E. KASIKOVA;
Inst. for the Care of Mother and Child, Prague 4, Czech Republic.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The aim of this study was to assess 1-year outcome of the polyacrylamid hydrogel (PAHG) transurethral injection in selected risk group of women with stress urinary incontinence (SUI).

Background:
Injection of bulking agents (BA) into the urethral wall can improve urethral coaptation. If conservative management fails, BA is the most minimal invasive therapy for stress urinary incontinence.

Methods:
This is an open, prospective, observational study of patients operated with the PAHG (Bulkamid®) technique at one center between September 2008 and December 2009. A total of 41 women with urodynamic stress incontinence with previous inefective anti-incontinence surgery and/or comorbidities that precludes anesthesia were prospectively assigned to this study (drop out at 12 months follow-up = 0 patients). Only 36% of patiens was without previous surgery for SUI and the reason for hydrogel aplication was presence of severe comorbidities. The majority of women (64%) underwent 1–3 ineffective procedures for SUI in the past. Exclusion criteria were: 1) post-void residual volume (PVR) greater than 100 mL, 2) women with stage II, III or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, 3) Q max<15 ml/s. Prior to the surgery and at 12 month follow-up cystometry, maximum urethral clousure pressure (MUCP), functional urethral length (FUL), maximum flow rate and cough test were performed. All patients self-evaluated the severity of their incontinence symptoms with the use of a visual analog scale (VAS). Quality of life (QoL) assessment was performed using the International Consultation on Incontinence Questionnaire-Short form (ICIQ-UI SF). Criteria of Cure: An objective cure was defined as a negative cough stress test with 300 mL of saline solution in the bladder during the multichannel urodynamic examination. Subjective evaluation of the procedure was made using the ICIQ-UI SF questionnaire. Subjective cure was defined by no leakage of urine after surgery (tick-box "never"was checked after surgery). Subjective improvement was experienced if assessment of frequency of urine leakage after the surgery was lower than before. Subjective failure occurred if the urine leakage frequencies before and after the surgery were identical or worse. Surgical procedures: For all patients, the procedure was performed under local para-urethral anesthesia supplemented by intravenous analgosedation. Minimally three deposits at Nr. 6, 10 and 2 were placed 1 cm distal to the bladder neck. After satisfactory urethral occlusion the bladder was emptied via the endoscope.

Results:
The mean age was 69 years (42–88), mean BMI 28.8 kg/m^2 (21.3–39.6), and mean parity was 2.4 (1–8). The mean operating time was 21.4 min. (10–45), the median injected volume per treatment was 1.28 ml (1–2.2.5).There were no major peroperative complications. Early postoperative complications (day 0–7):urinary tract infection - 4.9%, febrile morbidity - 2.4%, urinary retention - 4.9%. There was no clinical hematoma or bleeding in the early postoperative period. Late postoperative complications (day 8–28): urinary tract infection - 12,2%, febrile morbidity - 4.9%, urinary retention - 2.4%. At the 12-month follow-up 63% women were objectively cured. Regarding the parameters of subjective cure, where we analyzed the questionnaire parameters before and after surgery in each patient, we found following results: 10% women were subjectively dry and 68% were improved, 22% of patients evaluated their continence status without change or worse. The mean VAS score significantly decreased from a mean of 7.95±1.83 to a mean 3.89±1.45 (p). The ICIQ-SF questionnaire symptoms score also statistically significantly decreased from a mean of 15.00±3.57 before surgery to 10.65±4.65 at the 12-month follow-up evaluation. Urodynamic parameters at the 12-month follow-up showed statistically significant change in case of MUCP and FUL. PVR changes were not significant. PAHG can be visualized by transvaginal ultrasound. In the objective cured group (63%) PAHG deposits were visible by all patients. In the objective failure group (37%) the PAHG deposits were not visible by three patients. The possible reason for this phenomenon is leakage from the puncture holes or mucosal defect when the PAHG

deposits are placed too superficially and/or the deposits are too large.

Conclusions:

The current study proves that transurethral PAHG injection in selected group of women with SUI improve significantly the patients satisfaction and their continence. The procedure is quick and easy to performe and therefore well acepted by risk group of patients (obesity, comorbidities). The objective cure rate of 63% at 12 months follow-up in this selected group is acceptable.

Presentation Number: 177

EVALUATION OF PELVIC FLOOR DISORDERS AND PELVIC FLOOR MUSCLE FUNCTION IN NULLIPAROUS HIGH PHYSICAL ACTIVITY WOMEN.

M. P. DE ARAUJO[1], T. MASCARENHAS[2], T. H. DA ROZA[3], R. N. JORGE[4], M. PESTANA[2], J. A. SANTOS[5], R. A. CASTRO[1], M. J. GIRÂO[1], M. G. SARTORI[1];
[1]UNIFESP, Sao Paulo, Brazil, [2]FMUP-HSJ, Porto, Portugal, [3]IDMEC-POLO FEUP, Porto, Portugal, [4]IDMEC, FACULDADE DE ENGENHARIA DA UNIVERSIDADE DO PORTO, Porto, Portugal, [5]FADEUP, Porto, Portugal.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of this study was to evaluate pelvic floor disorders and pelvic floor muscle strength in nulliparous high physical activity women.

Background:

It has been published that female athletes reported urinary incontinence that may affect the performance and concentration (1). Stress urinary incontinence is seen in all sports involving abrupt repeated increases in intra-abdominal pressure, like trampoline, basketball and volleyball (2). However vaginal symptoms, pelvic organ prolapse and pelvic floor muscle function hasn't been established yet.

Methods:

Female active women from Faculty of Sport at University of Porto, Portugal were evaluated. The inclusion criteria were: regular sexual activity, regular menstrual cycle or use of hormonal contraception, nulliparous and high level of physical activity. Level of physical activity of each participant was assessment by the International Physical Activity Questionnaire (IPAQ) and only women with vigorous-intensity activities were included (IPAQ>3000 MET-minutes/week). As the initial assessment, the International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF), and the International Consultation on Vaginal Questionnaire Short-Form (ICIQ-VS) was performed. Pelvic organ prolapse diagnosis and quantification were made based on the pelvic organ prolapse quantification (POP-Q). Pelvic floor muscle strength assessing was made in a crook lying position by the Oxford muscle grading scale and using a digital precision perineometer (Peritron® 9300, Cardio-Design, Australia). The Ethics Committee at the São João Hospital, Porto, approved the study and all subjects gave written informed consent to participate. Statistical analysis was performed using Graph Pad Prism 4.0; p values≤0,05 were considered statistically significant.

Results:

A total of 46 active women with mean age of 21±3 years (range 17–34) and body mass index (BMI) 21±2 Kg/cm2 (range 17–27) were evaluated. Overall prevalence of UI was 38%. Incontinence severity was slight in the majority of the cases and impact on quality of life was low. Moreover, ICIQ-VS results show the absence of vaginal bulge symptoms. According to POP-Q stages, 85% of women were found to be in stage 0, 11% were found to be in stage I and 4% were found to be in stage II. The mean vaginal squeeze of rest was 37.4±12.10 cmH2O (range 12–70) and the mean of maximum squeeze pressure was 70.1±24.1 cmH2O (range 21–115). Continent and incontinent women did not differ in all parameters evaluated (table 2).

Table 1: Urinary incontinence and vaginal symptoms in nulliparous high physical activity women.

Questionnaire	Mean ± SD	Range
ICIQ-SF		
Question 1 (Frequency of urinary incontinence)	0.6±1.0	(0–5)
Question 2 (Amount of leakage)	0.9±1.3	(0–6)
Question 3 (Overall impact of urinary incontinence)	1.0±2.3	(0–10)
ICIQ-SF (0–21)	2.5±4.3	(0–21)
ICIQ-Vaginal Symptoms		
Vaginal symptoms (0–53)	1.8±3.1	(0–14)
Sexual matters (0–58)	2.7±8.4	(0–42)
Overall impact on quality of life (0–10)	0.5±1.5	(0–9)

Table 2: Comparison of continent and incontinent nulliparous active women according to age, body mass index, age of menarche and perineometry values.

	Incontinent group (mean ± DP)	Continent group (mean ± DP)	p value
Age (years)	22±4	20±2	0.24
Body mass index (Kg/cm2)	22±2	21±2	0.26
IPAQ questionnaire (MET-minutes/week)	6525±3993	6517±4893	0.7
Resting vaginal pressure (cmH2O)	36.4±14	38.1±11	0.66
Maximal vaginal pressure (cmH2O)	66+23.7	77.7±24.2	0.38

Conclusions:
Slight urinary incontinence but not vaginal symptoms were common in nulliparous high physical active women. There weren't statistically significant differences in pelvic floor muscle function measured by strength in continent compared with incontinent group. These results may be useful to create a new protocol to prevention and rehabilitation of pelvic floor muscles in female athletes.

References:
1. Urologia, 2010.
2. Int Urogynecol J Pelvic Floor Dysfunct, 2008.

Presentation Number: 178

OPTIMAL DURATION OF BLADDER CATHETERIZATION AFTER UROGYNAECOLOGICAL SURGERY

J. M. LEE, **H. C. HAN**, L. C. LEE, A. TSENG, H. F. WONG;
KK Women's & Children's Hosp., Singapore, Singapore.

Consent obtained from patients: Not Applicable
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To find out the optimal duration of bladder catheterization needed postoperatively after different types of urogynaecological surgery so as to reduce the need for repeat catheterisation.

Background:
Indwelling bladder catheterization is routinely used post operatively after vaginal prolapse and incontinence surgery to prevent bladder distension resulting from post operative pain or tissue oedema [1]. Bladder over-distension can have a negative impact on bladder function. The duration of bladder catheterisation varies considerably in different centres [2], and we are reviewing our data for the optimal duration of bladder catheterization post operatively.

Methods:
A retrospective review was done for all the urogynaecological surgeries in our hospital between the period of 1/9/2008 to 28/2/2009 (6 months). We reviewed the case sheets of 267 patients and collected data on the type of surgery done, day of which bladder catheter was first removed, amount of residual urine, number of days of catheterization till successful voiding (defined as residual urine (RU) less than 150mls), and total number of times of trial off catheter.

The current department protocol for anterior repair with or without mesh involves keeping the indwelling bladder catheter on for 2 days. A trial off catheter is done on the morning of the 2nd post operative day (POD). Patient is asked to pass urine whenever she needs. RU is measured with a bladder scan after 5 h. If RU is >150mls, the patient is recatheterised and a trial off catheter is done the next day. If the patient is still unable to void, she would be given an option of going home with the indwelling catheter and have a trial off catheter 1 week later in the clinic, or to stay in the hospital and repeat a trial off catheter 2 days later.

Our protocol for patients with tension free vaginal tape only procedure (TVT or TVT-O) involves a trial off catheter on the 1st POD. Some have a trial off void on the op day if they have general instead of spinal anesthesia. They could be day surgery cases.

Results:
There were a total of 267 patients. 95 patients underwent anterior repair excluding TVT-O or TVT, with or without vaginal hysterectomy. 74 underwent anterior repair without mesh, 10 underwent anterior prolift and 11 underwent total prolift. The cumulative percentage of patients who could void successfully (RU<150mls) was 59% on 2nd POD, 77% on 3rd POD, 86% on 6th POD and 97% on 12th POD.

92 patients underwent TVT-O or TVT excluding anterior repair, with or without vaginal hysterectomy. 90(97.8%) had TVT-O and 2(2.2%) had TVT. The cumulative percentage of patients who could void successfully was 25% on the day of operation, 88% on 1st POD and 100% on 2nd POD. Majority had their bladder catheter removed on 1st POD. Of those 30 patients who had their trial of void on the operation day, 22(73%) were able to void successfully.

57 patients underwent both anterior repair and TVT or TVT-O, with or without vaginal hysterectomy. The cumulative percentage of those who could void successfully was 70% on 2nd POD, 84% on the 3rd POD, 91% on the 6th POD and 98% on the 11th POD.

23 patients had urogynaecological surgeries without anterior repair or TVT or TVT-O (e.g. only vaginal hysterectomy, Manchester or posterior repair). 52% could void successfully on the 1st POD and 96% by the 2nd POD.

Conclusion:
Using 75% as an acceptable rate of successful voiding for the 1st trial off catheter after urogynaecologcal surgery, we recommend a trial off catheter on the 3rd POD for those with anterior repair without TVT or TVT-O as 77% can void successfully by that day. This is also applicable for those with anterior repair and TVT-O or TVT as 84% of these patients can void successfully by the 3rd POD.

We recommend a trial off catheter on the 1st POD for patients with TVT-O or TVT without anterior repair as 88% of them can void successfully on 1st POD.

For patients who had urogynaecological surgeries without anterior repair, TVT or TVT-O, we recommend a trial off catheter on the 2nd POD as 96% can void successfully on 2nd POD compared to only 52% on the 1st POD.

References:
1) (2010). *J Obstet Gynaecol Res,* 36(1): 154–158
2) (2004). *International J of Obstet and Gynae*, 111(8): 828–830

Presentation Number: 179

OFFICE-BASED URETHRAL BULKING INJECTION FOR WOMEN WITH STRESS URINARY INCONTINENCE: AN EVALUATION OF PATIENT ACCEPTANCE AND TOLERABILITY

J. MOBLEY, III, A. SMITH, G. DAVILA, G. GHONIEM;
Cleveland Clinic Florida, Weston, FL.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
Our primary objective was to assess patient experience of urethral bulking agent (UBA) injection as an office-based procedure in terms of patient tolerability and acceptance. Secondarily, we compared two local anesthetic regimens to determine any differences in tolerability.

Background:
The use of UBA as a treatment for stress urinary incontinence (SUI) secondary to intrinsic sphincter deficiency (ISD) is well established. While the vast majority of these procedures are performed in the operating room, the desire and expectation to increase office-based procedures is expanding. Our institution performs urethral bulking in an office-based setting, and it was our goal to evaluate patient experience with this procedure using only a local anesthetic.

Methods:
We performed a prospective evaluation of all patients who underwent in-office transurethral injection of silicone particles (Macroplastique®; Uroplasty, Minnetonka, MN) for a diagnosis of SUI with ISD between November 2010 and February 2011. All patients received local anesthetic with 10 cc of viscous lidocaine placed intraurethrally 10 min prior to the procedure. Additionally, based on surgeon preference, some patients received 5 cc of 1% lidocaine injected periurethrally at both the 3 o'clock and 9 o'clock position. A 22 F rigid cystoscope with a 20 gauge endoscopic needle was used to perform the urethral bulking. Immediately following the injection, patients responded to a questionnaire assessing their tolerance and perception of the procedure. All items were assessed with a 10 point VAS scale with "1" universally corresponding to a positive experience and "10" corresponding to a negative experience. The questionnaire consisted of three questions asking:

- "Did you find this to be an acceptable office-based procedure?"(Question 1)
- "Please rate your overall level of pain during this procedure?" (Question 2)
- "How likely would you be to recommend this procedure to a friend based on your overall experience?" (Question 3)

Patient demographics and questionnaire responses were recorded and compared. Statistical analysis was performed.

Results:
During the study period, 34 treatment naïve women underwent UBA injection and completed the postprocedural questionnaire. Overall, in-office injection of UBA was very well tolerated and resulted in no significant complications (Table 1). For question 3, 30 patients (88%) reported a score of "1" indicating that they were very likely to recommend this office-based procedure to a friend. A sub-analysis comparing 13 women who received only viscous lidocaine to 21 women who additionally received lidocaine injection revealed no significant differences in patient acceptance, tolerability or the likelihood that they would recommend the procedure to others.

Table 1. Patient tolerability

	Question 1 n=34	Question 2 n=34	Question 3 n=34
Patient response			
• Mean & SD	1.3±0.9	3.9±2.8	1.3±1.0
• Median	1 (1–5)	3 (1–10)	1 (1–5)
Anesthetic complications	0		
Postoperative complications	0		

Conclusion:
This study revealed that in-office UBA injection utilizing only local anesthesia is highly acceptable and well tolerated. These results persisted despite the type and method of local anesthesia used. While further studies are certainly needed, our data suggest that the injection of urethral bulking agent can be performed in the office setting with minimal risk and high patient satisfaction.

Presentation Number: 180

EFFICACY OF THE SUPPORT UNDERWEAR IN PAROUS FEMALES WITH STRESS URINARY INCONTINENCE

S. NINOMIYA[1], I. SAITO[1], H. OKAYAMA[2], K. MASAKI[2], Y. SAITO[2], S. MORIKAWA[2], Y. ENDO[2];
[1]Kobe Univ. Graduate Sch. of Hlth.Sci., Kobe, Japan, [2]Shiga Univ. of Med. Sci., Shiga, Japan.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To verify whether the use of the support underwear was recovered from stress urinary incontinence (SUI).

Background:
SUI is a considerable women's health problem that is caused by descent of the bladder and pelvic relaxation in parous females. We reported that the use of support underwear was effective for the elevation of the bladder neck and its effect was compatible to the contraction of pelvic floor muscle.

Methods:
The subjects were 21 parous women with SUI (27–64 years of age). They wore the support underwear (Style Science®, Wacoal corp., Japan; Fig. 1) in daytime of 12 weeks with usual activities. The

symptoms of SUI (60 min pad test, international consultation incontinence questionnaire-short form; ICIQ-SF, frequency of incontinence episodes per week and frequency of voiding in a day) and the position of the bladder neck were compared between before and after 12 weeks use of the support underwear. Sagittal T_1-weighted images of the pelvis on the position of the bladder neck were acquired in a sitting position using an open MR system, GE SIGNA SP/2. The distances from the pubococcygeal line (PC line) to the bladder neck were measured (Figure.2) [1].

Results:

The results of 21 subjects were summarized in Table 1. After 12 weeks, ICIQ-SF, frequency of incontinence episodes per week and frequency of voiding in a day were significantly decreased. In addition, the position of the bladder neck was significantly higher after than before the 12 weeks use of the support underwear.

Conclusion:

The support underwear was effective to relieve SUI. The elevation of the bladder neck and the disappearance of incontinence without the underwear after 12 weeks might possibly have been strengthened pelvic floor muscle. The use of the support underwear might be an easy and inexpensive method for the treatment of SUI.

Reference:

[1] Radio graphics.22:295–304, 2002.

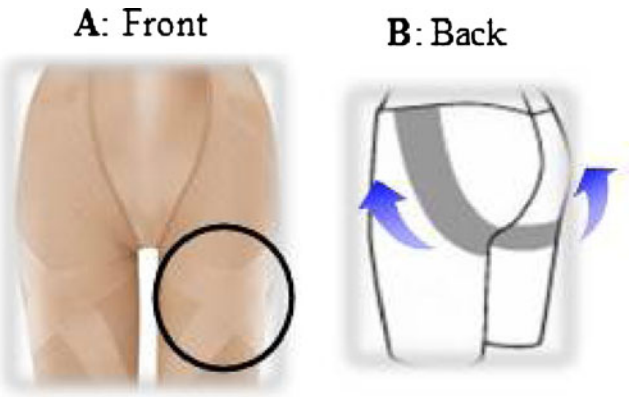


Figure 1. The Support underwear, Style Science®, Wacoal Co., Japan

A; The cross structure (Circle) stimulates the upper leg muscle, and it induce to big steps. As a result, the muscle of the hip can be strengthened by walking about 6000 steps/day, wearing about 5 hours/day and using about 12 weeks.

B; The pelvis supported from the side of the lower side of the back.

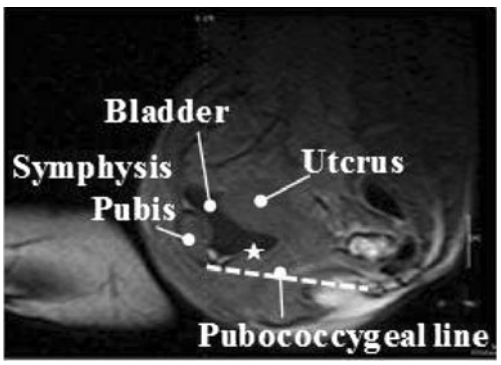


Figure 2. Method to measure the position of the bladder neck. The position of the bladder neck (asterisk) was measured by the distance from the pubococcygeal line (dotted line).

Table 1. Patient characteristics, symptoms of SUI and the position of the bladder neck (n= 21)

	Before Me(25-75th parcentile)	after Me(25-75th parcentile)	p-value
Patient Characteristics			
Age(years)	40.0(34.5–57.0)		
BMI(kg/m2)	21.0(19.9–23.1)		
Nomber of deliveries(times)	2.0(1.0–2.0)		
Symtoms of SUI			
60 minutea pad test(g)	0.0(0.0–1.5)	0.0(0.0–0.0)	0.058
ICIQ-SF(point)	8.0(5.5–11.0)	5.0(0.5–6.0)	0.001
Frequency incontinence episodes per week(times)	3.0(2.0–7.5)	0.0(0.0–1.0)	$p<0.001$
Frequency of voiding in a day(times)	7.7(6.2–8.9)	7.0(5.6–7.8)	0.008
The position of the bladder neck(mm)	−2.0(−9.7–5.0)	4.5(−7.5–9.1)	0.012

Presentation Number: 181

SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA™) VS TRANSOBTUARTOR TAPE (OBTRYX™) : PROSPECTIVE COMPARATIVE STUDY AT A MEDIAN FOLLOW-UP OF 6 MONTHS

P. SMITH, A. ARUNKALAIVANAN, M. BAPTISTE;
City Hosp., Birmingham, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The purpose of this study is to determine whether Single-incision Midurethral tape (Ophira™) and Transobtuartor tape (Obtryx™) suburethral sling procedures have equivalent patient satisfaction and clinical efficacy in the treatment of stress urinary incontinence alone or the stress component in mixed urinary incontinence.

Background:

Tension-free vaginal tape (TVT) is known to be a successful treatment for SUI. In 2001 Delorme used the 'outside-in' technique of a transobturator route for suburethral tape placement-the transobturator tape (TOT). This technique reduced the risk of bladder perforation and injuries to the bowels and large vessels compared with TVT. The cure rates of both procedures were similar, ranging from 90% to 95% [1]. Despite its improved safety profile and excellent cure rates, the procedure still involves passing needles through the groin which in certain patients can result in groin pain. Although the risk is very low, especially with the outside-in approach like the TOT tape, the risk still exists.

There have been various single-incision mid-urethral tapes involving only one incision in the vagina and no needle passages through the abdomen or groin developed (2). We aim to evaluate the efficacy of Ophira™ comparing the Obtryx™ at a median 6 months' follow-up.

Methods:

A total of 61 women between January 2009 and August 2010 were prospectively self-selected for either Ophira™ (30) or Obtryx (31) procedure based upon their choice of anaesthetic. They were offered to either Ophira (under local anaesthesia) or Obtryx (under general anaesthesia) in our unit. An informed consent was obtained in all cases. The procedure was performed in an ambulatory day case setting.

Power calculation suggests that estimated minimum sample size for an unpaired two sample Student-*t* test should be 23 experimental subjects. However, acknowledging the possibility of loss to follow-up, poor RNIE data collection and withdrawal of consent, our minimum target was 30 women. This project was approved by the clinical effectiveness department of the unit.

As part of the preoperative workup, a case history was compiled for all consecutive patients, together with a physical examination and urodynamic evaluation when indicated. All women had positive cough stress test (CST) preoperatively when on full bladder with at least a bladder volume of 250 ml on bladder scan.

Objective cure was defined when physical examination of the patient yielded a negative cough stress test, while subjective cure was assessed based on woman's perception of improvement in stress urinary incontinence symptoms (significantly improved, same, worse) at the 6 month follow up visit.

Statistical analysis of the data was performed by using Student's *t*-test, chi-square test, and Fisher's exact test, for which SPSS ver. 16.0 (SPSS Inc., Chicago, IL, USA) was used. Statistical significance was set at $p<0.05$.

Results:

Table 1. Baseline characteristics

Variable	Ophira™(30)	Obtryx™ (31)	P* value
Age	57.1±13.3	52.7±9.1	0.26
Parity	3±1.6	2.8±1.2	0.9
Pre-op Cough stress test (CST) + ve	22(73.6%)	24(77.4%)	0.55
UDSUI	16(53.3%)	17(54.8%)	0.57
Pure SUI	11(36.7%)	8(25.8%)	0.18
MUI	3(10%)	5(16.1%)	0.57

* *Chi-Square test*

Table 2. Follow-up at 6 months

Variable	Ophira™	Obtryx™	P* value
Significantly improved	28 (93.3%)	29(93.5%)	0.68
Same	2(6.7%)	2(6.5%)	1.0
Positive CST	3(10%)	2(6.5%)	0.67
Negative CST	27(90%)	29(93.5%)	0.62

**Fisher's exact test*

Baseline characteristics were matched between both groups. In Ophira™group, the mean Wong-Baker pain score is 1.07±1.258 during the procedure.

Conclusion:

After a follow-up period of 6 months, the Ophira™ and Obtryx™ procedures were comparable in terms of both objective and subjective cure rates. However the major advantage of Ophira™ when compared to TVT or TOT is the possibility of performing this procedure under local anaesthesia on an ambulatory basis with less post-operative pain and intra operative complications. However, studies are needed to establish further long-term and large-scale follow-up outcomes of the procedures.

References:

1.BJOG (2007)114: 522–531

2.Int Urogynecol J Pelvic Floor Dysfunct. 2011 Mar;22(3):335–9.

Presentation Number: 182

PUDENDAL NERVE STRETCH REDUCES EXTERNAL URETHRAL SPHINCTER ACTIVITY IN RATS

K. P. SAJADI[1], D. L. LIN[2], B. M. COURI[1], C. M. DISSARANAN[1], P. J. ZASZCZURYNSKI[2], H. JIANG[1], B. BALOG[1], J. M. KERNS[1], M. S. DAMASER[1];

[1]Cleveland Clinic, Cleveland, OH, [2]Cleveland VAMC, Cleveland, OH.

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

Objective:

Vaginal childbirth injury, a major risk factor for stress urinary incontinence (SUI), results in damage to the pelvic floor and the innervation of the external urethral sphincter (EUS) via pudendal nerve stretch (PNS) and crush [1]. However, current animal models of childbirth injury emulate pudendal nerve injury via crush or transection only.

We hypothesize that PNS reduces EUS electromyography (EMG) activity with a resultant decrease in urethral resistance, as measured by leak point pressure (LPP).

Background:

Animal models such as vaginal distension (VD), pudendal nerve crush (PNC), and combinations simulate SUI, but they are recoverable [2]. Durable animal models of SUI exist, such as pudendal nerve transection and urethrolysis, but they involve drastic injuries with no physiologic correlates in human childbirth. An integrated model involving physiologic mechanisms of injury, such as pudendal nerve crush and stretch and VD, if non-recoverable, would more accurately replicate human vaginal childbirth injury.

3D models of human childbirth suggest significant PNS occurs during vaginal childbirth, with 13% strain to the branch that innervates the EUS [1]. Animal models of peripheral nerve injuries indicate that stretch of this degree results in significant nerve impairment [3], but no such model of PNS exists.

Methods:

Female virgin Sprague–Dawley rats were anesthetized with urethane. The urethra and bilateral pudendal nerves were exposed through an anterior transpubic approach. EMG of the EUS was performed during bladder filling via a suprapubic catheter (5 mL/h). The pudendal nerve was marked with a surgical marker and bilateral PNS was performed by insinuating either a shodded Debakey forceps or Castroviejo surgical calipers under the nerve and opening the instrument, stretching the nerve by spreading apart the ischiorectal fossa between the pelvic sidewall and vagina. Digital photographs before and during stretch were used to quantify nerve stretch. EUS EMG was repeated immediately following and 10 min after bilateral stretch, and compared to pre-stretch values. Similarly, LPP was assessed at each timepoint as a measure of urethral outlet resistance. Friedman test followed by pairwise comparisons were used to evaluate results at different time points with $p<0.05$ indicating a significant difference.

Results:

Eleven rats weighing approximately 260 g underwent bilateral PNS. Mean ± SEM stretch was 45±11% on the left, and 45±12% on the right. EMG results before, immediately and 10 min after stretch are compared in Table 1. There was an immediate and significant reduction in EMG amplitude ($p=0.016$) and frequency ($p=0.008$). Ten minutes after PNS, amplitude and frequency remained significantly lower than pre-stretch ($p=0.021$ and $p=0.004$, respectively). LPP decreased after stretch, and improved 10 min later (Table 1), but the differences were not statistically significantly ($p=0.097$). The change in EUS EMG amplitude and frequency correlated with the percentage of PNS in individual animals (Spearman $\rho=-0.77$, $p=0.016$, and $\rho=-0.82$, $p=0.007$).

Conclusions:

PNS shows promise as a model of pudendal nerve injury during vaginal childbirth, with demonstrable change in EUS EMG immediately following stretch that remains impaired 10 min later. Statistically significant differences in LPP were not seen, but the EMG changes suggest neuromuscular dysfunction that has not recovered during the time period studied. The changes in EMG, and relationship between these changes and degree of stretch, warrant further study with different degrees and durations of stretch, and longer follow-up to evaluate the time course of recovery. Further study is also necessary to better delineate the

longer term effects of PNS on continence, histology, and innervation of the EUS.

References:
1. AJOG 2005; 192: 1669.
2. Curr Opin Obstet Gynecol 2010; 22: 425–9.
3. Oper Tech Orthop 2004; 14: 153–62.

Table 1. EMG and LPP outcomes before and after nerve stretch. Data are presented as mean ± SEM.

	Before Stretch	Post-Stretch	10 min Post-Stretch
Mean Amplitude (μV)	6.6±1.9	4.6*±1.0	4.6*±0.96
Frequency (Hz)	106±29	40*±8.2	47*±13
LPP (cm H2O)	39±6.4	30±7.1	44±8.1

* indicates significantly different from before stretch

Presentation Number: 183

FRESH MUSCLE FIBER FRAGMENTS ON A SCAFFOLD: A POTENTIALLY NEW CONCEPT FOR PELVIC FLOOR RECONSTRUCTION?

M. BOENNELYCKE[1], L. CHRISTENSEN[2], L. F. NIELSEN[3], S. GRÄS[1], **G. LOSE**[1];
[1]Copenhagen Univ. Hosp. Herlev, Herlev, Denmark, [2]Copenhagen Univ. Hosp. Bispebjerg, Copenhagen, Denmark, [3]Coloplast A/S, Humlebaek, Denmark.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To investigate in a rat model if methoxypolyethyleneglycol-poly (lactic-co-glycolic acid) (MPEG-PLGA) scaffolds seeded with either autologous in vitro cultured muscle-derived cells (MDC) or autologous fresh muscle fiber fragments (MFF) could be used for tissue repair.

Background:
Synthetic, permanent meshes have gained popularity in order to improve outcome of pelvic floor reconstructive surgery. However, multiple complications have emerged. Recently, in vitro cultured muscle-derived cells seeded on biodegradable scaffolds have been proposed in the treatment of pelvic organ prolapse. A biodegradable scaffold with fresh muscle fiber fragments, collected at the time of surgery, is a simpler and faster approach circumventing the disadvantages of in vitro culture of cells.

Methods:
Twenty scaffolds with autologous in vitro cultured muscle-derived cells (MDC) and twenty scaffolds with autologous fresh striated muscle fiber fragments (MFF) were implanted subcutaneously on the abdomen of rats, two in each rat, and examined after 3 (ten of each preparation) and 8 weeks (ten of each preparation). Growth pattern of MDC and MFF was assessed by immonohistochemistry, and biocompatibility was assessed by histopathology.

Results:
At 3 weeks, both MDC and MFF were identified. However, the growth patterns of the two were different: MDC were finely distributed as single cells within the scaffold, whereas the MFF were localized as fragmented striated muscle fibers beneath the scaffold.
At 8 weeks, fragmented striated muscle tissue was generated from the MFF in six of ten explants, while the MDC had vanished.
The scaffolds showed a high degree of biocompatibility, and were present at 3 weeks, but not at 8 weeks.

Conclusions:
Autologous fresh muscle fiber fragments on a MPEG-PLGA scaffold seem to be useful for tissue repair. This technique bypasses the technically demanding, costly and time-consuming in vitro processing of muscle-derived cells.
This study introduces a promising new concept with possible implications for the surgical reconstruction of pelvic organ prolapse.

Presentation Number: 184

DIFFERENTIAL GENE EXPRESSION IN UTEROSACRAL LIGAMENT AND FULL THICKNESS ANTERIOR VAGINAL TISSUES FROM PATIENTS WITH RECURRENT AND PRIMARY PELVIC ORGAN PROLAPSE

M. M. FIEGEN[1], K. M. EYSTER[2], K. D. BENSON[1], K. A. HANSEN[1], P. VANEERDEN[1];
[1]Univ. of South Dakota Sch. of Med., Sioux Falls, SD, [2]Univ. of South Dakota Sch. of Med., Vermillion, SD.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: No

Objective:
The objective of this study was to profile differential gene expression in three distinct patient groups. We hypothesised that a differentially expressed gene pattern would be seen in women with recurrent pelvic organ prolapse (POP).

Methods:
Our groups consisted of five women with recurrent POP, five women with primary POP and four women without POP. Whole human genome DNA microarray analysis technology was used to test this hypothesis in patients with recurrent POP compared to patients with primary POP and non-prolapse controls. The tissue evaluated was anterior vaginal wall tissue and uterosacral ligament (USL) tissues obtained at the time of each women's primary surgery. This study has undergone Institutional Review Board approval at Sanford Health and also the University of South Dakota. Patients enrolled have provided written informed consent.

Results:
The evaluation of vaginal and USL tissues yielded more than 450 genes each found to be differentially expressed by 2 fold or greater. We identified in USL tissue 10 genes of interest. Eight genes were

over expressed and two genes were under expressed. Confirmation of degree of gene expression for these ten genes was performed by using the technique of real-time RT-PCR. The vaginal tissues contributed no genes of interest. We found that five of the eight genes which were over expressed functioned in the task of distribution, metabolism or deposition of adipose tissue. The two genes of greatest interest that were under expressed in USL tissue were the HOXD genes D10 and D11. These two genes have been identified in earlier microarray studies as being under expressed in patients with POP.

GeneSpring 7.0 software (Agilent was used to perform ANOVA on the data from statistical analysis of the DNA microarrays; P value set at 0.05. The real-time RT-PCR data was analysis using STAT/SE 9.2 (StataCorp, College Station, TX). We used one way ANOVA, with the assumption that the cycle threshold (Ct) means are normally distributed. We confirmed significance of this data using the non-parametric Kruskal-Wallis test since data normality cannot be confirmed with such small numbers. P value set at 0.05.

Conclusions:

The most important finding of this study was the identification and recognition of a group of genes found to be over expressed in uterosacral ligament tissue. The function of many of these genes was related to the deposition or differentiation of adipose tissue within USL tissues. This event would be expected to have the effect of weakening this pelvic support structure. The two under expressed HOXD genes seen in the recurrence group only are known to affect change/weakening of the USL's when found to be absent or under expressed.

This project tested the hypothesis that differential gene expression could be used to identify patients with recurrent POP. Indeed, the data showed our hypothesis to be correct.

Demographic Means

	G1	G2	G3	
Age	52.75+2.7	61.2+10.5	69.6+14.0	NS
Parity	1.5(0–3)	2.6(2–4)	2.8(1–5)	NS
BMI	37.36+8.6	27.54+3.2	30.56+8.3	NS

Presentation Number: 185

Consent obtained from patients: Not Applicable

Level of support: Not Applicable

Work supported by industry: No

DUAL VAGINAL VAULT SUPPORT AT COLPORRHAPHY—AN ANATOMICAL BASIS FOR A FOUR-PART VAGINAL REPAIR

B. T. HAYLEN[1], D. VU[2], S. VASHEVNIK[3], K. TSE[2];
[1]ST VINCENTS CLINIC, SYDNEY, Australia, [2]Univ. OF NEW SOUTH WALES, SYDNEY, Australia, [3]ST VINCENTS Hosp., SYDNEY, Australia.

Objective:

We aim to establish an anatomical argument for the simultaneous use of the uterosacral and sacrospinous ligaments to provide dual vaginal vault support at colporrhaphy. This is on the basis of: (A) the consideration of the top of the vagina as a "vault" or an "area" rather than as an "apex" or a "point", the former requiring wider or perhaps dual support; (B) the technical ability to use both ligaments concomitantly; (C) the different vectors through which these ligaments might synergize to provide that dual (and hopefully balanced) vaginal vault support.

Background:

(A) The top of the vagina is termed (1) a "vault" i.e. a "continuous arch" covering the vagina rather than an "apex" which is defined generically as "the highest point". Support to a "vault" implies that more than one direction of support might be necessary, perhaps, as a minimum, anterior and posterior vault support.

(B) Midline plication of the uterosacral ligaments simultaneous with anterior colporrhaphy has been recently described (2) as providing anterior Levels 1 and 2 vaginal support. Sacrospinous colpopexy and posterior colporrhaphy has long been used to provide posterior Levels 1 and 2 vaginal support. Dual vaginal vault support is technically possible but anatomically untested.

Methods:

(C) A study was made of 13 formalized cadaver hemipelves in our collection of teaching prosections. None had undergone hysterectomy or obvious pelvic floor repair surgery. Four observers were involved in the studies. In all cases, observations were made to determine (i) the vector of anatomical support provided by (a) traction on the uterosacral ligaments at a level of the vaginal vault and (b) traction on the posterior vaginal vault towards the (right) sacrospinous ligament. Additional observations were made of which vaginal walls were subject to increased tension as a result of the above traction. Traction was by forceps or sutures in the line of the respective ligaments.

Results:

(a) Traction on the *uterosacral* ligaments caused a *posterior and superior* vector of tension on the *anterior* vaginal vault (and wall) with minimal or no tension on the posterior vaginal vault (and wall).

(b) Traction on the posterior vaginal wall (right side) towards the right *sacrospinous* ligament caused also a *posterior and superior* vector of tension on the *posterior* vaginal vault (and wall) with minimal or no tension on the anterior vaginal vault (and wall). To a certain degree, it may be slightly lateral, dependent on the area of attachment of the supportive suture to the ligament.

(c) Traction on both the *uterosacral* ligaments and traction on the posterior vaginal vault towards the *sacrospinous* ligament created tension in both anterior and posterior vaginal walls and a more balanced elevation of the vaginal vault. Tension on the sacrospinous ligament was infero-lateral to that by the uterosacral ligament.

Conclusions:

1: *Dual Uterosacral and Sacrospinous ligament traction* is technically possible to provide *dual* anterior and posterior support to the vaginal vault at colporrhaphy (anterior and posterior).

2: This dual vaginal vault support, *posterior and superior* (uterosacral) and also *posterior and superior* (sacrospinous)

appears balanced and necessary for effective vaginal vault (and wall) support.

3: The use of anterior and posterior colporrhaphies and combined uterosacral and sacrospinous ligament support to the anterior and posterior aspects of the vaginal vault creates a *four-part vaginal repair* not previously described.

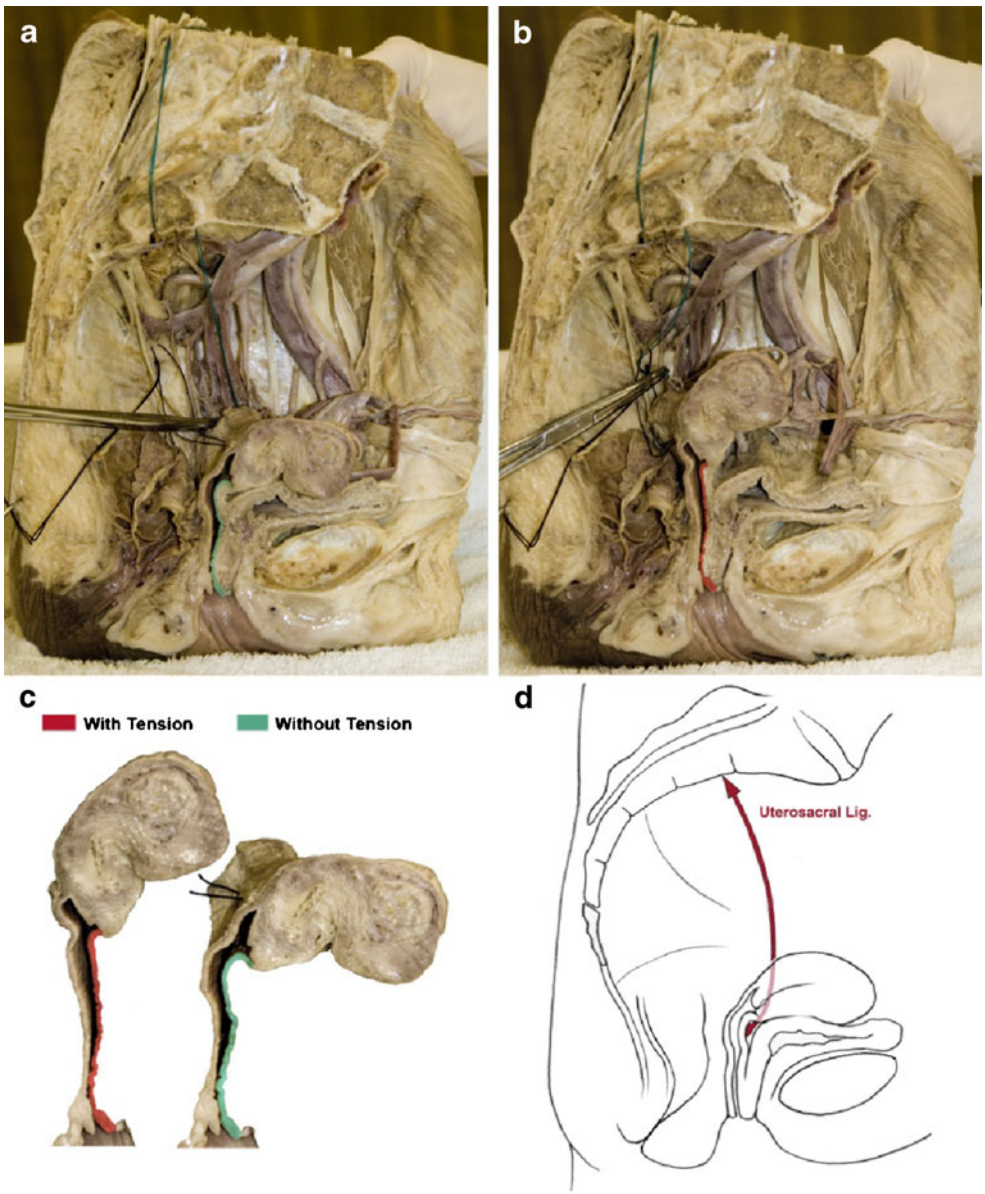
References:

1: Int Urogynecol J, 2010; 21:5–26

2: Int Urogynecol J, 2011; 22:69–75.

Figure:

An example of the support of one (the uterosacral) of the two ligaments: (A) under no tension in the hemipelvis; (B) under tension in the hemipelvis, the latter creating tension in the anterior vaginal wall. (C) An image of the uterus and vagina "with" and "without" tension on the uterosacrals and in turn the anterior vaginal wall. (D) The vector of tension on the anterior vaginal wall created by traction on the uterosacral ligaments.



Presentation Number: 186

IMPROVING THE DIAGNOSIS OF URINARY TRACT INFECTION—UROTHELIAL CELL SEDIMENT CONCENTRATES CULTURED ON CHROMOGENIC AGAR

S. SATHIANANTHAMOORTHY, R. KHASRIYA, **A. S. KUPELIAN**, K. GILL, J. MALONE-LEE;
UCL, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
The aim of the study was to test the efficacy of a new 24-h system for urinary spun sediment culture so as to bring this enhanced improved method of urine culture closer to ordinary clinical practice

Background:
A series of publications from different centres have recently cast grave doubts on the veracity of routine urine cultures [(1)]. There is a growing body of evidence, from disparate sources, that a large proportion of women with urinary tract infection go undiagnosed because of the widespread reliance on the discredited techniques. It is all very well to criticise what is accepted practice, but providing an alternative, appropriately simple, reliable replacement is a formidable challenge.
UTI is initiated by bacterial adhesion to urothelial cells, microbial endocytosis, cellular colonisation, and subversion of immunity. The bladder retaliates against infection by use of the innate immune system. A significant early component of the complex defence cascade is to shed uroepithelial cells in an attempt to expel the infected cells from the body. These outcasts can be harvested from the urine and concentrated by centrifuge.
An unselective culture of urinary cell sediment suspensions has been shown to overcome the inadequacies of routine culture, separating normal controls from patients with symptoms and discriminating different degrees of disease. Unfortunately the reported method using blood agar, required CSU, and was time consuming and ill-suited to ordinary clinical practice [(2)].
For clinical utility, a more efficient MSU method is required. We have designed a serviceable 24-h system for routine practice.

Methods:
Meticulous MSU specimens were obtained from 24 female OAB patients at varied treatment stages and 8 controls. Cell sediment was extracted from 5 mls of urine by centrifuge at 2000 rpm for 5 min and resuspended in 400 μl of 0.01 M phosphate buffered saline solution. 50 μl aliquots were inoculated onto columbia blood agar (CBA) and chromogenic agar (CPS3) plates. Analytical profile index (API) tests were used to identify species. A separate survey of 186 subjects analysed data on sediment cultures to compare clinical states as opposed to methods.

Results:
Eight controls were negative on all urinalysis & cultures. 12 patients (50%) showed microscopic pyuria (≥10 wbc μl^{-1}); 8 (33%) showed positive routine culture (≥10^5 cfu ml^{-1}); 19 (79%) had positive sediment cultures mean=10^2 cfu ml^{-1} sd=$10^{1.5}$). Bland-Altman plot showed good method agreement (Fig. 1) except when *Proteus* and *Pseudomonas* swarmed. Fig. 2 illustrates survey sediment culture data from 186 patients obtained at different stages of treatment, and controls subjects. The discriminatory power of the method, despite the heterogeneous sample is well shown.

Conclusions:
(1) OAB patients exhibit UTI undetected by routine analysis. (2) The newer sediment culture method offers a solution to a major problem for ordinary clinical practice.

References:
1. J.Urol., 2010; 183, 1843–1847.
2. Neurourol.Urodyn., 2009; 8, 779–780.

Figure 1

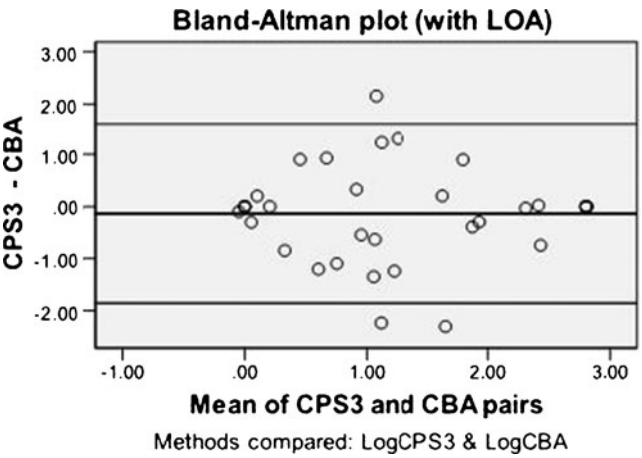
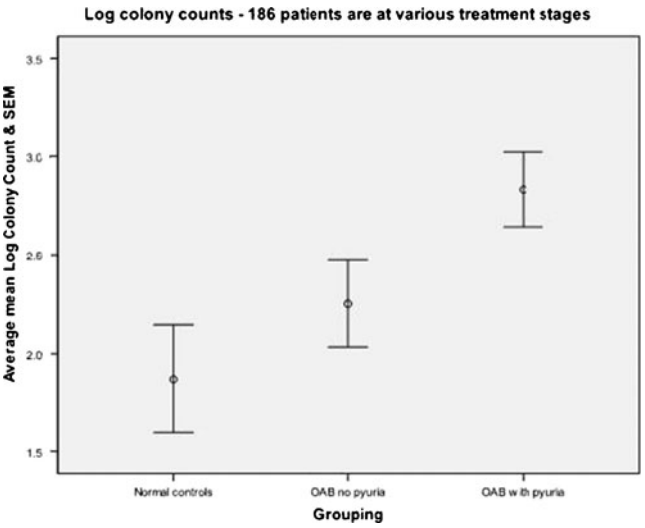


Figure 1



Presentation Number: 187

TOWARS POLYPROPYLENE MESH VIZUALISATION ON MRI

V. LETOUZEY[1], S. HUBERLANT[1], O. GUILLAUME[1], S. BLANQUER[1], L. LEMAIRE[2], X. GARRIC[1], R. DE TAYRAC[1]; [1]CRBA, Montpellier, France, [2]PIAM, Angers, France.

Consent obtained from patients: No
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objective:

To visualize synthetic mesh in case of surgical pelvic organ prolapse (POP) repair with polypropylene mesh placement. To associate to polypropylene mesh a contrast agent which should permit to identify mesh in the pelvis by MRI. Mesh must be seen at different time and on different clinical used MRI (1.5 Tesla (T), 3 Teslas).

Background:

When pelvic organ prolapse has been identified as symptomatic, an important part of its treatment is surgery. The main indication of synthetic mesh placement on pop repair is to prevent recurrence.

Synthetic meshes are on controversies about complications as pelvic pain, re intervention for vaginal erosion or *de novo* dyspareunia. Last facts have concluded to a common used of polypropylene mesh by vaginal route and possible by laparoscopy.

The better morphologic exam on pelvis seems to be MRI, the most reproducible. Pelvic ultrasonography is limited to bone inter position and to operator limits.

As a minimal invasive surgery, pop recurrence mechanisms are unknown. Pelvic pain is difficult to associate to mesh complication.

To understand, manage and optimize polypropylene mesh used on pop repair (vaginal or laparoscopic route), a good follow up visualization on pelvic MRI would be of great interest, but polypropylene meshes are not spontaneously visible on MRI.

Methods:

Gadolinium was chosen as a contrast agent in the form complexed with diethylene triamine pentaacetic acid (DTPA). Two polymers have been grafted covalently: a resorbable (Poly Capro Lactone, PCL), the other non-absorbable (poly methyl acrylate, PMA). We conducted a coating polypropylene mesh with these grafted polymers.

The MRI evaluation was performed on a 7 Teslas research MRI, and on 1.5 Tesla and 3 Tesla clinical MRI.

Visualization and tolerance have been studied both in vitro and in vivo in Wistar rats in a model of double dorsal implantation intramuscular and subcutaneous.

Tolerance in vivo was performed by investigating gadolinium in various organs of the model and histological analysis of adjacent organs.

Animal manipulations were made under an agreement of an ethics committee.

Results:

We got a prosthetic display in vitro and in vivo, on the different MRI, with better visibility and a tolerance for non-absorbable polymer. (Fig. 1). Fig. 1 shows a wistar rat with 4 dorsal meshes implantation, 2 coated meshes at the left of the spina (2.5x0.5 cm intramuscular & 2.5x1cm subcutaneous) and 2 athe right no coated.

A = dorsal rat implantation 3D Abdominal pelvis reconstruction, on 1.5 T MRI

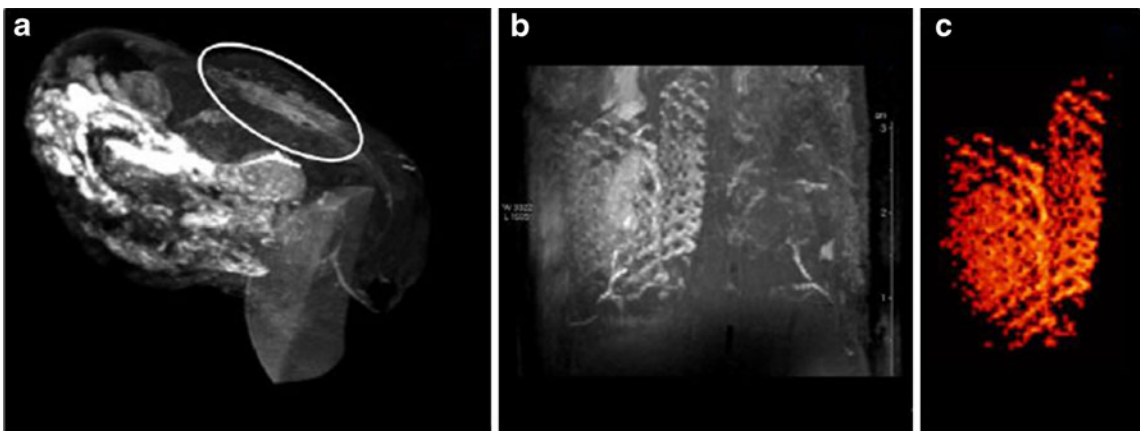
B = Left side coated meshes and right side no coated meshes

C = 3D reconstruction of the both coated meshes

The clinical tolerance and the toxicology results of the coated meshes were satisfactory at 18 months follow up.

Conclusions:

For the first time graft have been viewed both with a research engine (7 T) and on a conventional clinical MRI (1.5 and 3 T), and this both in vitro and in vivo.



Presentation Number: 188

3-D IMAGING AND QUANTIFICATION OF VAGINAL TISSUE ELASTICITY UNDER NORMAL AND PROLAPSE CONDITIONS

H. VAN RAALTE[1], V. LUCENTE[2], V. EGOROV[3];
[1]Princeton Urogynecology, Princeton, NJ, [2]The Inst. for Female Pelvic Med., Allentown, PA, [3]Artann Lab., Trenton, NJ.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The objective of this study is to assess the clinical suitability of a new approach for 3-D imaging and quantification of vaginal tissue elasticity under normal and prolapse conditions.

Background:
Changes in the elasticity of vaginal walls, connective support tissues and muscles are thought to be significant factors in the development of pelvic organ prolapse. To date, there is no standardized, non-invasive, reproducible tool to accurately assess the circumferential elastic properties of the vagina. In prior studies, we clinically tested the Vaginal Tactile Imager (VTI) which allows for tissue imaging at specified locations in vagina and assessment of tissue elasticity by means of introduced elasticity index [1]. VTI is based on principles similar to those of manual palpation. It is capable of visualizing tissue mechanical structure by measuring surface stress patterns under tissue deformation using a pressure sensor array [2].

Methods:
Thirty one women were enrolled in the study (clinical trials identifier NCT01111916). The study subjects included 18 women with normal pelvic support and 13 women with pelvic organ prolapse (Stage I-III). Average age was 60±17 (range 28–90). The transvaginal probe comprised of 128 pressure sensors and a 3-D motion tracking sensor covered by disposable sheath used with ultrasound lubricant. The images were obtained and recorded in an office setting at the time of routine vaginal examination. Three orthogonal projections of 3-D vaginal tactile image with VTI probe location are observed by operator in real time. The Pelvic Organ Prolapse Quantification (POP-Q) system for prolapse classification. Tissue elasticity (Young's modulus) was calculated from spatial gradients in resulting 3-D tactile image. Each VTI examination took 3–5 min.

Results:
All 31 women were successfully examined with the VTI device. 3-D images of the vagina were recorded and stored. We found substantial differences in anatomy and tissue elasticity between normal and prolapse conditions. Average values for tissue elasticity for anterior and posterior compartments for normal conditions were 7.2±4.9 kPa and 6.6±4.0 kPa respectively. For Stage III prolapse the average values for tissue elasticity for anterior and posterior compartments were 1.6±0.9 kPa and 1.7± 1.1 kPa respectively. Figure 1 and Figure 2 present examples of examination results for normal and prolapse conditions. The patients were asked to assess comfort level of the VTI examination relative to manual palpation: 77% said that VTI procedure is the same, 20% less comfortable, and 3% more comfortable. No adverse events were reported.

Conclusions:
Our findings suggest that VTI is suitable for 3-D imaging of the vagina and provides quantitative assessment of vaginal tissue elasticity. VTI offers insight into individual variations in biomechanical properties of vaginal tissues to further our understanding of prolapse and optimize surgical repairs.

The work was supported by the National Institute on Aging, USA, Grant 1 R43 AG034714-01

References:
1. IEEE Trans. Biomed. Eng. 2010; 57(7):1736–44.
2. Int. J. Med. Inf. 1998; 49: 195–216.

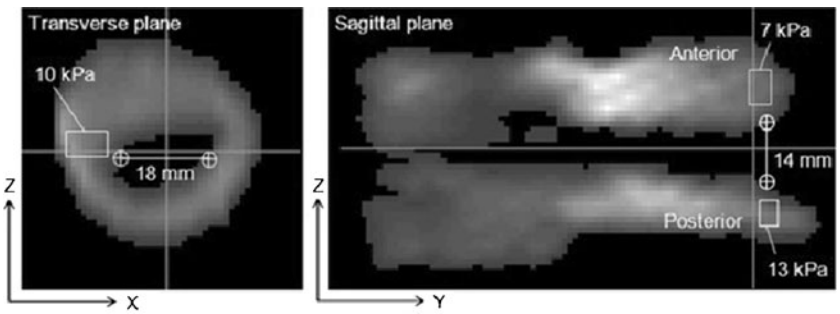


Figure 1. Transverse and sagittal cross-sections of 3-D vaginal tactile image received with VTI for a patient (63 y.o.) with normal pelvic floor conditions as was detected by manual palpation during physical examination. Young's modulus was calculated for areas specified by the rectangular markings.

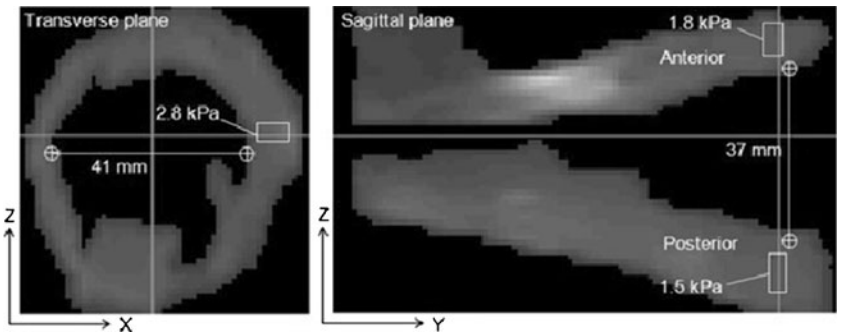


Figure 2. Transverse and sagittal cross-sections of 3-D vaginal tactile image obtained with VTI for a patient (77 y.o.) with Stage III prolapse in anterior and upper half of the posterior compartment that recurred less than one year from a vaginal hysterectomy and traditional anterior repair.

Presentation Number: 189

WHAT HAVE WE LEARNED FROM BASIC SCIENCE FOR MESH COMPLICATION IN PELVIC FLOOR RECONSTRUCTIVE SURGERY? FROM INFECTION TO POLYPROPYLENE DEGRADATION?

V. LETOUZEY[1], A. CORNILLE[1], P. MOURTIALON[1], X. GARRIC[1], J. LAVIGNE[2], R. DE TAYRAC[1];
[1]CRBA, Montpellier, France, [2]ESPRI INSERM 26, Nimes, France.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To explore the pathogenesis of prosthetic complications, our study aims to determine the stages between infection and erosion. Using a model of mesh infection we experimentally tested Clave's conclusion [1] regarding a correlation between infection and polypropylene "degradation".

Background:
Pelvic organ prolapse surgery uses prosthetic reinforcements to reduce recurrence. Specific complications occur in at least 5% of cases (prosthetic vaginal erosions). The assumptions are many and the infection is rarely found. However, the prostheses explanted from patients have an electron microscopic appearance of varnish which may correspond to a bacterial biofilm or to a degradation of polypropylene. A subclinical mesh infection, acquired during the initial implantation, may result in wound separation with subsequent mesh exposure.
In a recent study we observed a significant correlation between infection and shrinkage [2].

Methods:
Ex vivo explanted meshes for the surgical treatment of symptomatic vaginal erosion, has been observed by scanning electron microscopy (SEM).
In vivo, we implanted mesh in a rat model of incisional hernia and abdominal infected with E. coli during repair surgery. Polypropylene meshes were implanted in the incisional abdominal hernia model in Wistar rats and inoculated with 10^6 CFU of Escherichia coli, as described previously [2]. After 30 days the meshes were explantated and washed with DMSO (dimethyl sulfoxide) and ultrasonic shock, then examined by Environmental Scanning Electron Microscope (ESEM).
In vitro, polypropylene mesh was placed in wells containing culture medium with or without bacteria (E. coli).
At the same time, polypropylene meshes were inoculated in vitro with the same isolate of Escherichia coli, then explanted after 2–15 days and washed with the same process.
We studied the clinical, bacteriological and ESEM prosthetic characteristics.

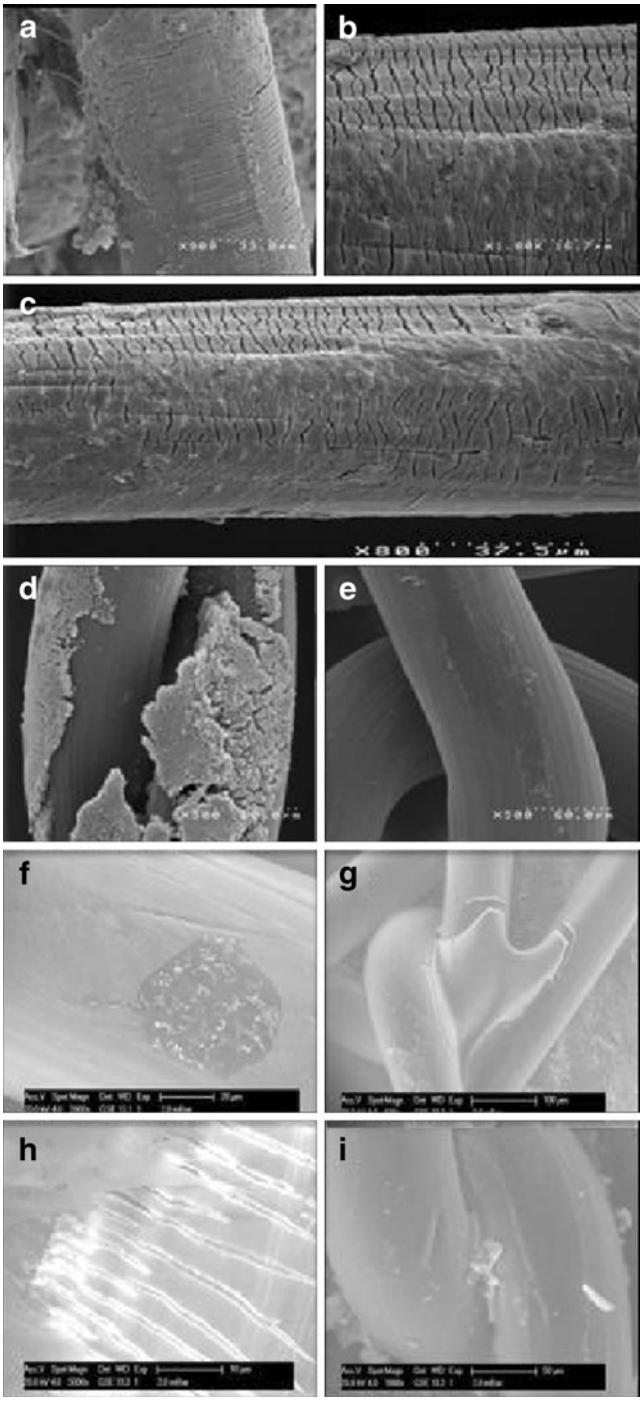
Results:
(Figure 1)
In these studies we also observed signs of superficial degradation and transverse cracks on explanted mesh from patients (A&B), in vitro and in vivo infected meshes, but this appeared to concern only the biofilm, with no effect on the implant thread itself.
This film is not found in control groups not infected.
After cleaning meshes, analysis revealed that the underlying polymer is intact.
Scanning electron microscopy of low weight, macroporous, monofilament knitted polypropylene mesh extracted after 30 days with infection by *E. Coli* in an incisional abdominal hernia model in Wistar rats. The explanted infected mesh shows transverse cracks (C). After washing with DMSO (D) and ultrasonic shock (E), it appears marked modifications in mesh surface corresponding to the biofilm (C), and after biofilm removal, no polymer degradation was seen any more (E).
Environmental Scanning Electron Microscopy of in vitro infection of low weight polypropylene macroporous knitted mesh extracted from a bacterial culture medium infected by *E. Coli* after 2 (F), 5 (G) and 15 days (H). Figure 1.F shows the beginning of biofilm formation. Figure 1.G shows cracks in the biofilm at mesh interstices. Figure 1. H shows transverse cracks in the biofilm. Figure 1 I shows non-degraded polymer thread after washing out the biofilm.

Conclusions:
The prosthetic infection, thus forming a bacterial biofilm acts as a coating and would be associated with prosthetic erosions, without changing the underlying polymer.
This study allows us to reproduce experimentally the microscopic appearance of meshes clinically complicated and requiring surgical intervention.

References:

1. Clavé A, et al. (2010) Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J Pelvic Floor Dysfunct. 21(3):261–70.

2. Mamy L, Letouzey V, JP Lavigne et al. (2011) Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J Pelvic Floor Dysfunct 22(1):47–52.



Presentation Number: 190

MATHEMATICALLY MODELED MEMBRANE TENSION VALUES IN PELVIC FLOOR PATIENTS

Y. OZOG[1], K. HAEST[1], E. WERBROUCK[1], F. VAN DER AA[1], F. CLAUS[1], D. DE RIDDER[1], J. DEPREST[1], E. MAZZA[2]; [1]Univ. Hosp. Leuven, Leuven, Belgium, [2]ETH, ZURICH, Switzerland.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

(1) to develop a mathematical model in order to calculate membrane tension by applying Laplace's Law (2) to generate a range of membrane tensions at the urogenital hiatus and midpelvis in patients with and without prolapse, based on actual dimensions

Background:

Klinge (1996) proposed a mathematical model to calculate membrane tensions present in the abdominal wall, which resulted in the famous 16 N/cm cut off value for abdominal wall hernia repair. Such information is lacking for prolapse patients.

Methods:

(1) MODEL: The pelvic cavity can be represented by a (half) ellipsoid, with the pelvic floor tissues forming its boundaries. We empirically selected two cross sections, i.e. the outlet and the midpelvis. A two dimensional section at these levels defines an ellipse with a *semimajor axis* 'a' and a *semiminor axis* 'b'. For the *outlet* the semimajor 'a' is half the distance between the inferior posterior border of the symphysis and the posterior border of the external anal sphincter. Semi-minor 'b' is half the distance between the medial border of the pubococcygeus muscle at the level of the perineum. For the *midpelvic* plane (across the spines) semimajor 'a' is half the distance between the upper posterior border of the symphysis and the inferior border of sacral vertebra 5. Semiminor axis 'b' is half of the interspinal distance.

(2) MEASUREMENTS: We conducted a retrospective study on randomly selected archived pelvic floor ultrasound images in prolapse (n=50 grade II or higher) and non-prolapse patients (n= 50 grade 0-I) to determine urogenital dimensions. Ultrasound and clinical assessment (POP -Q score) were done by a single operator (EW). Midpelvic measurements were done on CT-images acquired for other unrelated problems (non-prolapsed). A 64-slice CT-scanner with slice width 1.0 mm was used, offline analysis by MeVisLab software (MeVis Medical Solutions AG, Bremen, Germany)(KH). Abdominal pressure (P; cm H_2O) recordings were made in 10 consecutive patients undergoing urodynamics (Delphis IP, Laborie, Toronto, ON, Canada). Abdominal pressures were recorded in the supine (as for CT) and upright position (as for ultrasound). Observations during minimum 3 coughs and 3 valsalva episodes were recorded and averaged. Outcomes are displayed as mean ± SEM.

Results:
(1) mathematical model : We adapted Laplace's Law, stating that the forces within a container (F_{in}) are in equilibrium with the forces within its walls (F_w). The internal forces (F_{in}) are defined by the abdominal pressure (P_{ABD}) on the (inner) surface of the ellipse, being equal to π.a.b. The force inside the tissues (F_w) is defined by the stress inside these tissues σ, their thickness (T) and the circumference of the ellipse, approximated by Ramanujan (1962): $C \approx \pi[3(a+b) - \sqrt{((3a+b)(a+3b))}]$. The stresses inside the pelvic structures (σ) can then be calculated as follows: $\sigma(N/area) \approx (P_{ABD}.a.b.\pi)/T.\pi[3(a+b) - \sqrt{((3a+b)(a+3b))}]$ or, in brief, $\sigma \approx (\mathbf{P.a.b.}\pi)/\mathbf{T.C}$. In order to allow actual calculation, we assumed that tissues are a single layer, so that stresses can be reduced to membrane tensions, Mt, independent of the thickness: $\mathbf{Mt} = \sigma\mathbf{T} \approx (\mathbf{P.a.b.}\pi)/\mathbf{C}(\mathbf{N/m})$.
The direction and orientation of the membrane tension is the tangent at the ellipsoid at the level of these anatomical 'ellipses' (alpha, expressed in °). The true membrane tension at a certain anatomical point therefore is: $\mathbf{Mt\ true} = \mathbf{Mt}/\mathbf{sin}(\alpha) = \sigma\mathbf{T} \approx (\mathbf{P.a.b.}\pi)/\mathbf{C}.\ \mathbf{sin}(\alpha)(\mathbf{N/m})$.
(2) Actual measurements. (Table 1). Membrane tension at the outlet ranges from 0.8 N/cm (rest) to 1.76 N/cm (at valsalva). Being a larger anatomical structure, the tissues in the pelvic inlet are prone to a membrane tension of 1.49 N/cm (in rest). In prolapse patients, the membrane tension at rest is 0.89 N/cm (ns), raising to 2.14 at valsalva (p<.0001). The current methodology does not allow us to measure alpha.

	CT study (midpelvis)	Ultrasound study (outlet)	
POP	No prolapse	No prolapse	prolapse
Age	57(±16)	58.06 (±14.69)	63.5 (±10.60)
Parity	2.XX	2	2.24
Weight	74,03 (±18,26)	67.84 (±13.42)	72.00 (±11.46)
Height	166,14(± 6,71)	1.64 (±0.05)	1.63 (±0.08)
Conditions at measurement	Laying down, at rest	Half sitting, at rest	Half sitting, at rest
Pressure (range; N/cm²)	0.54 (0.09–0.91)	0.64 (0.26–1.21)	1.28 (1.06–1.58)
Semimajor a (cm)	6.72 (±0.49) (rest)	2.95 (±0.46) (rest)	3.27 (±0.45) (rest)
N.A.	3.25 (±0.57) (valsalva)	3.8 (±0.50) (valsalva)	
Seminajor b (cm)	4.74 (±0.35)	2.195 (±0.33) (rest)	2.45 (±0.43) (rest)
		2.4 (±0.40) (valsalva)	3.0 (±0.35) (valsalva)
Membrane tension (range; N/cm)	1.49 (0.25–2.51)	0.80 (0.33–1.52) (rest)	0.89 (0.36–1.69) (rest)
		1.76 (1.46–2.17) (valsalva)	2.14 (1.77–2.64) (valsalva)

Conclusions:
We calculated a membrane tension at the urogenital hiatus at rest of 0.8–0.89 N/cm, being comparable in patients with and without prolapse (with comparable outlet dimensions). Outlet Mt at maximal valsalva raises by a factor 2.2–2.4 as compared to rest. Membrane tension for non-POP patients is 20% lower than in POP patients. Membrane tension is lower for a smaller structure like the outlet which might be counter-intuitive. However, the presence of bony structures provide local support, thus reducing the tension in the tissues present. We propose to repeat this study in a set of patients were as many measurements can be combined as possible and using MRI, so that alpha can be measured as well.

Presentation Number: 191

A RANDOMISED TRIAL OF CYSTOSCOPY AND URETHRAL DILATATION VERSUS CYSTOSCOPY ALONE IN WOMEN WITH OVERACTIVE BLADDER SYMPTOMS AND VOIDING DYSFUNCTION

M. BASU, J. DUCKETT;
Medway Maritime Hosp., Gillingham, Kent, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The primary objective of this trial was to assess whether a urethral dilatation is associated with any relief of overactive bladder symptoms (OAB) in women with OAB and objective evidence of voiding dysfunction.

Background:
Cystoscopy and urethral dilatation (UD) have been advocated as empirical treatments for women with lower urinary tract symptoms. A recent survey of practice amongst UK urologists found that 61% had performed UD 7 or more times during the year in which the survey was conducted, although 55% believed that less than half of the patients experienced long term improvement[1]. Recently published retrospective outcome data revealed a short term subjective improvement in urgency of 33%; this fell to 19% at 6 months[2]. It can be postulated that the mechanism of action of any improvement in urgency associated

with urethral dilatation in women with OAB symptoms involves an improvement in voiding via a decrease in urethral resistance. The poor overall long term efficacy may be due to the nature of the urethral tissue, and the fact that any outflow resistance was functional rather than mechanical. A 1988 RCT of UD versus cystoscopy in women with dysuria showed UD to confer no additional symptomatic benefits[3]. There are no published randomised trials assessing the effect of UD in women with OAB, despite the fact that it is a procedure that is performed relatively frequently.

Methods:

This was a parallel randomised trial with an allocation ratio of 1:1. All women with significant overactive bladder symptoms and objective evidence of voiding dysfunction were eligible to enter the trial. This was a single centre trial in a large UK district general hospital. The inclusion criteria were bothersome OAB symptoms (based on scoring 1 or 2 on the Urgency Perception Scale, UPS) and a maximum flow rate of less than 15 ml/s on a voided volume of over 200mls. Eligible patients were randomised on the day of surgery to undergo either cystoscopy alone or cystscopy plus urethral dilatation. Subjects were randomised using a block randomisation sequence, with allocation to each group being via a series of sequentially numbered opaque envelopes. Due to the sample size, random allocation using the population as a single block was undertaken. Subjects were blinded as to the intervention carried out. Follow up was at 6 weeks consisting of a urodynamic test and symptom assessment. The primary outcome measure was cure of urgency at 6 weeks based on scoring 3 on the UPS. The secondary outcome measure was change in voiding parameters in each group at 6 weeks. A priori power calculation was carried out to determine the required sample size, based on a cure rate for urgency of 0.4 for the urethral dilatation arm (from pilot data) and 0.1 for the cystoscopy alone arm. For a power of 80% and a significance level of 0.05, it was calculated that a total of 50 women would need to be randomised. Ethical approval was granted by the local Research Ethics Committee and informed consent was taken from each patient.

Results:

A total of 50 women were randomised into this study. Data from all randomised patients was included in the analysis. 22 women were randomised to undergo urethral dilatation and 28 to undergo cystoscopy alone. The groups were equal in terms of age, parity, menopausal status and the presence of overactive detrusor contractions. 10/22 women in the UD arm reported resolution of urgency at 6 weeks versus 5/28 in the non-UD arm (odds ratio 0.32, 95% confidence interval 0.09–1.19). There was no significant change in voiding parameters post-operatively in the UD or non-UD arm. There was one case of bladder rupture in the non-UD arm and 6 cases of new onset USI (2 in the UD arm, 4 in the non-UD arm).

Conclusions:

UD confers no additional symptomatic benefit above cystoscopy alone in women with OAB symptoms. This suggests that it is not a useful management option in women with OAB and voiding dysfunction, although this may be further explored in a multi-centre context.

References:

1.Ann R Coll Surg Eng 2006; 88: 496–498
2.Int Urogynecol J Pelvic Floor Dysfunc 2009; 20: 1073–1077
3.Br J Urol 1988; 61: 500–504

Presentation Number: 192

INCREASED NERVE GROWTH FACTOR IN OVERACTIVE BLADDER: IS IT CAUSED BY INFECTION?

G. VIJAYA[1], P. GALLO[1], A. DERPAPAS[1], R. CARTWRIGHT[2], G. DIGESU[1], C. DELL'UTRI[1], R. FERNANADO[1], V. KHULLAR[1]; [1]ST.MARY'S Hosp., LONDON, United Kingdom, [2]Inst. OF REPRODUCTIVE AND DEVELOPMENTAL BIOLOGY, IMPERIAL Coll., LONDON, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:

The aim of our study was to evaluate the effect of antibiotic therapy on urinary Nerve Growth Factor (NGF) in women with treatment resistant overactive bladder (OAB) and detrusor over-activity (DO).

Background: OAB and DO have a multi-factorial aetiology, but may present as a manifestation of cystitis associated with chronic subclinical infection. Electron microscopy in rodent models demonstrates that Escherichia coli have the ability to invade the bladder epithelium and to mature into biofilms [1]. These biofilms create a chronic quiescent reservoir in the bladder, and serve as a source for recurrent cystitis in patients with non-infected urine. It has been also shown that fastidious organisms are usually not detected by routine urine culture methods, thus they may also contribute to a chronic subclinical infection if not treated. These data seem to justify the use of antibiotics in patients with DO and OAB.

NGF is one of the neurotrophic factors released by urothelium and smooth muscle. Clinical and experimental data demonstrated a direct link between increased levels of NGF in bladder tissue and urine and OAB, DO and bacterial infection. In the light of these data some authors have suggested that NGF levels could be considered as a biomarker for OAB as well as for the assessment of therapeutic outcome in patients with OAB or DO [2].

Methods:Women with OAB were recruited for this study if they matched three main criteria: 1) Failure to respond to anticholinergics 2) Urodynamic confirmation of DO and 3) Cystoscopic appearances and bladder biopsy histology consistent with chronic cystitis. Following informed consent participants were treated with

a 6 week course of rotational antibiotics. A 3 day bladder diary, a King's Health Questionnaire, Patients' Perception of Bladder Condition questionnaire (PPBC), and Patients' Perception of Intensity of Urgency Scale (PPIUS) were used before and 6 weeks after antibiotic therapy. A clean catch midstream specimen of urine was collected before and after treatment. Urine samples were immediately centrifuged at 3000 rpm at 4° C for 10 min. 3 ml of urine was also sent for measurement of urinary creatinine. The centrifuged supernatant urine was stored at −80°C, until processing. Urinary NGF levels were measured using the NGF Emax ImmunoAssay System (Promega, Madison, WI, USA). The total urinary NGF levels were further normalized to the concentration of urinary creatinine (NGF/Cr level). Urinary NGF levels were compared before and after antibiotic therapy using Wilcoxon signed rank test, and with levels from a parallel control group of asymptomatic women using Mann Whitney *U* test.

Results:

In total 62 women (35 symptomatic and 27 asymptomatic) were studied. The mean NGF level in the control group was 0.076 (SD±1.39). The mean NGF level in the symptomatic group measured preoperatively was 5.47 (SD±1.9). There was a significant difference between the mean NGF levels between the control and the symptomatic group (p value<.05).

The NGF level significantly decreased after six weeks of antibiotic therapy as shown in Table 1 (p=0.015)

Mean	Standard deviation	*p*
Pretreatment	5.47±1.9	0.015
After 6 week course of antibiotics	1.9±2.3	

Table 1. NGF levels before and six weeks after antibiotic therapy. OAB symptoms were also significantly improved by antibiotic therapy as shown in Table 2.

	Pretreatment	After 6 week course of antibiotics	*p*
PPBC	4.66 (±1.57)	2.54 (±1.56)	0.001
PPIUS	3.03 (±1.74)	1.91 (±1.12)	0.001

Table 2. OAB symptoms before and six weeks after antibiotic therapy. Values are expressed as: mean (standard deviation).

Conclusions:

For women with treatment resistant DO and chronic subclinical cystitis, antibiotic therapy is associated with a parallel improvement in both OAB symptoms and urinary NGF levels. Subclinical infection may play a role in the pathogenesis of OAB and DO. Further studies are mandatory to confirm our hypothesis.

References:

1.Science. 2003 Jul 4; 301(5629):105–7.
2.Rev Urol. 2010 spring; 12(2–3):e69–77.

Presentation Number: 193

EFFECTIVENESS OF MID-URETHRAL SLINGS IN MIXED URINARY INCONTINENCE: A SYSTEMATIC REVIEW AND META-ANALYSIS

P. JAIN, P. LATTHE;
Birmingham Women's Hosp., Birmingham, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

To evaluate the effectiveness of midurethral slings in women with mixed urinary incontinence (MUI) by systematic review of the literature and meta-analysis.

Methods:

Systematic literature search was carried (up to February 2010) using relevant search terms in Medline, EMBASE, CENTRAL and Google Scholar. Relevant randomised controlled trials (RCT) & prospective studies were selected and data was collated by two independent reviewers.

Main results:

There was 6 randomized trial and 7 prospective studies with average to good quality included. There was heterogeneity in outcomes reported. The overall subjective cure from 7 prospective studies was found to be 56.4% (95% confidence interval 45.7–69.6%) at 34.9+/− 22.9 months follow up. The overall cure of UUI component was 30–85% at a follow-up of few months up to 5 years. Most of the studies described that this cure does not persist over the time. The cure rate of SUI following MUS varies from 85% to 97%. Long-term follow-up revealed persistent cure of stress component over time. The follow up period for the RCTs varied between 6-31 months. The odds ratio for overall cure of symptomatic MUI with or without USI+DO confirmed on UDS (5 studies, 641 women), was similar in women who underwent TVT vs. TOT (OR 0.96; 95% CI 0.42–2.13).

Conclusion:

The midurethral slings (TVT vs. TOT) offer similar overall cure in MUI. The evidence from nonrandomized studies suggests, persistent and good cure of stress component & the cure of the urge component is variable but less than stress component.

Presentation Number: 194

PAIN SYMPTOMS AS PART OF THE OAB COMPLEX

A. S. KUPELIAN, C. CHALIHA, K. GILL, L. BRACKENRIDGE, H. HORSLEY, J. MALONE-LEE;
Univ. Coll. London, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
To describe the treatment response of a pain score in patients with overactive bladder (OAB).

Background:
Symptom scores have been developed for OAB, stress urinary incontinence (SUI) and lower urinary tract symptoms (LUTS). Pain or nociception are less well served. In 1997, the Interstitial Cystitis Association UK conducted a survey of members (N=736), providing an exhaustive dataset on their disease experience. Eight recurring nociceptive or pain symptoms were identified. This framework was used to construct eight questions entered into a clinical symptom database; they were included in the assessment of all patients with previously untreated LUTS presenting to the incontinence clinic. In 2009, an analysis of this data was reported . These questions, applied more generally outside the boundaries of the painful bladder syndrome (PBS), functioned impressively as a measure of nociceptive symptoms. Internal consistency, construct validity, internal and external responsiveness were all confirmed. These questions discriminated between those with and without pyuria, and those with or without bacteriuria, distinguishing patients with urinary tract infection (UTI) contributing to OAB or LUTS. Data on longitudinal changes associated with disease treatment were lacking.

Methods:
Between 2002 and 2010, data were collected on dysaesthetic symptoms (Table 1). These were recorded using a fixed protocol, prospectively, from patients at presentation, and whilst under treatment. Symptoms of urgency were measured using a validated score. At each assessment, an MSU was obtained. The urine was examined by microscopy to quantify pyuria, and sent for routine culture (diagnostic threshold of 10^5 colony forming units ml^{-1}). Patients with pyuria and/or bacteriuria were treated for a presumed UTI with antibiotics. LUTS were treated according to standard guidelines. Clinicians were blinded to urinalysis results.

Table 1 Pain and nociceptive symptoms described by patients in the incontinence clinic 2002–2010

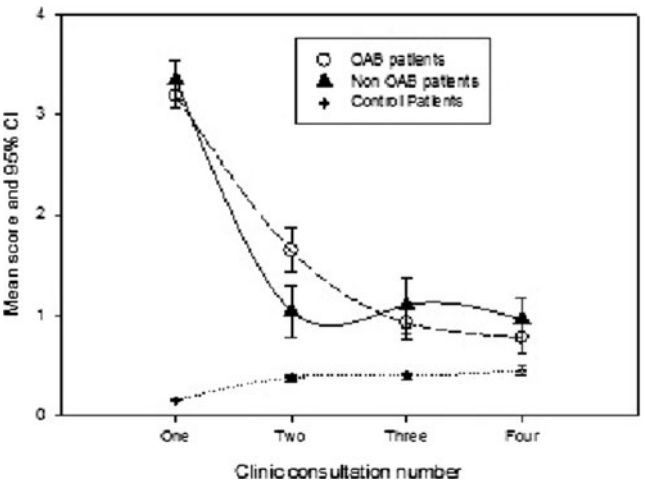
Symptoms	Frequency (%)
1. Pain/discomfort with bladder filling	51
2. Dysuria	45
3. Loin pain	44.5
4. General abdominal pain	22.8
5. Suprapubic pain/discomfort	15.6
6. Pain/discomfort radiating to legs	13.1
7. Iliac fossa pain/discomfort	8.8
8. Genital pain/discomfort	7.5

Results:
958 women presenting with at least one dysaesthetic symptom contributed to 8822 assessments (mean age=51, sd=19). At presentation 73% had OAB; 31% OAB and SUI; 8% SUI; 19% had dysaesthetic symptoms without LUTS. 30% had pyuria and 8% positive culture. Patients with voiding disorders were excluded from the analysis. 1057 similar women, presenting without pain, provided control data over 2854 consultations. Higher pain scores were associated with OAB, pyuria and antibiotic use; lower scores were associated with antimuscarinic use (t=14, p<.001). OAB and pyuria had a synergistic effect on the pain score. Dysuria was absent in 55%. The urgency score and pain score did not correlate (R=0.08, p<.0001). There was a clear treatment response (Fig. 1. F=16, p<.0001). OAB patients demonstrated a slightly slower recovery than those without OAB. The contrast with controls was striking. Amongst controls, there was no difference between those with, or without OAB.

Conclusions:
Pain symptoms, typically associated with PBS, occur independently in association with OAB, and pyuria, even though dysuria may be absent. These symptoms are important because they appear to be present in a subset of OAB patients, and remain distinct from urgency.

References:
1. Proceedings of the International Continence Society, San Francisco, 2009.
2. J Urol 2008; 179: 1000–05.

The pain scores at first amd three follow up visits OAB compared with no OAB



Presentation Number: 195

EXPRERSION OF IGF-1 SPLICE VARIANTS IN DETRUSOR MUSCLE. A NEW MUSCLE REPAIR MECHANISM PRESENT IN NORMAL AND PATHOLOGICAL BLADDER.

E. CORTES[1], E. CHIN-SMITH[2], C. KELLEHER[1], R. M. TRIBE[2];
[1]Div. of Women's Hlth., Guy's & St Thomas' Hosp., London, United Kingdom, [2]Div. of Women's Hlth.KCL and King's Hlth. Partners, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:
To demonstrate expression of IGF-1 splice variants as markers of an ongoing muscle repair mechanism present in bladder detrusor muscle.

Background:
The presence of an autocrine repair mechanism involved in the regeneration of damaged tissues has been demonstrated in muscle [(1)]. Our research has also demonstrated the presence of this mechanism in smooth muscle. According to these findings, during normal physiological bladder distension, muscles such as the detrusor would be subjected to this repair mechanism responsible for a constant cell turnover and repair of any damage. This is governed by different isoforms of the IGF-1gene, which as a result of stretching or injury splices into two variants known as Mechano Growth factor (MGF) or IGF-1Ec, and IGF-1Ea. Research to date [(2)], has shown that initially MGF promotes differentiation of stem cells into muscle precursors or myoblasts, followed by IGF-1Ea at a later stage which facilitates their progression to functional myofibers.

We hypothesize that for conditions such as detrusor overactivity (DO), this muscle repair mechanism may be faulty leading to poor muscle fibre turnover and muscle function. The present study aims to demonstrate the expression of these two IGF-1 splice variants in bladder detrusor muscle from patients with normal and abnormal bladder function. Understanding their normal and deficient expression may prime future studies on the pathophysiology of DO and the potential for new therapies

Methods:
Patients attending urogynaecological surgery were recruited to take part in the study. All patients underwent a saline diagnostic cystoscopy and bladder biopsy at the end of their scheduled procedure. Prophylactic antibiotics were given intraoperatively to reduce risk of infection. Two bladder samples were obtained from each candidate and placed in RNALater. Total RNA was extracted using Trizol Reagent® and cDNA synthesized using an Omniscript RT kit (Qiagen). mRNA expression of IGF-1Ea and MGF was determined by quantitative reverse-transcriptase polymerase chain reaction (qPCR) using SYBR Green Chemistry (Bioline) on a RotorGene 6000 (Qiagen). Normalised data are expressed as target gene copy number/housekeeping gene (GAPDH) copy number

Results:
Twelve patients were recruited for this pilot study. No intra or post operative complications were seen related to the bladder sampling procedure. As seen in table 1, samples were obtained from asymptomatic patients undergoing prolapse surgery, patients with mixed urinary symptoms, (associated or not with DO) and patients with painful bladder syndrome (PBS). In all cases, both splice variants were expressed. Normalised expression data are presented in Fig. 1

Conclusions:
This is the first time IGF-1 splice variants have been shown to be expressed within the detrusor muscle. The presence of this muscle repair mechanism in the normal and pathological bladder, opens a new door to the understanding of detrusor dysfunction and may ultimately provide insight into the pathophysiology and future treatment options for OAB.

References:
1. Insulin-like growth factor-1 gene splice variants as markers of muscle damage in levator ani muscle after the first vaginal delivery. AJOG (2005) 193, 64–70
2.Expression and splicing of the insulin-like growth factor gene in rodent muscle is associated with muscle satellite (stem) cell activation following local tissue damage. J Physiol. 2003 Jun 1;549(Pt 2):409–418

*Table 1. Patients recruited for cystoscopy and bladder biopsy. SUI: stress urinary incontinence; PBS: painful bladder syndrome; USI: urodynamic stress incontinence; DO: detrusor overactivity; N/A: Not applicable; VVF: vesico vaginal fistula; * = copy numbers relative to GAPDH.*

Patient	Age	Presenting Problem	Urinary symptoms	Urodynamic results	Antimuscarinic treatment	MGF*	IGF-1Ea*
1	54	Menorrhagia	None	N/A	N/A	0.8848	1901.12
2	56	Prolapse	None	N/A	N/A	0.0024	0.8958
3	64	Prolapse	None	N/A	N/A	0.0050	0.0543
4	91	Prolapse	Mixed	USI/No DO	Nil	0.0023	0.193
5	48	Prolapse	Mixed	USI/DO	YES	0.0054	0.160
6	53	Prolapse	Mixed	USI/No DO	YES	0.0039	0.1455
7	64	Recurrent SUI	Mixed	USI/No DO	In the past	0.0435	95.105
8	52	SUI	Mixed	USI/No DO	YES	0.0025	0.0980
9	65	PBS	Pain	No USI/No DO	Nil	0.0195	2.281
10	91	PBS	Pain/SUI/Freq	USI/No DO/LCB	Nil	0.0178	0.3066
11	86	PBS	Pain	No USI/No DO	YES	0.0487	0.5522
12	26	VVF	Continuous leakage	No USI/No DO	Nil	0.0071	0.2898

Presentation Number: 196

THE ANTIBIOTIC TREATMENT OF OAB COHORT

K. GILL, R. KHASRIYA, A. KUPELIAN, L. BRACKENRIDGE, H. HORSLEY, S. SATHIANANTHAMOORTHY, J. MALONE-LEE; UCL, London, United Kingdom.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

To report the outcomes of a treatment model for OAB that incorporate the use of antibiotics to treat a presumed chronic urinary tract infection(UTI)

Background:

A growing body of evidence signifies that in a group of patients, infection and an inflammatory process lies at the heart of the overactive bladder (OAB). The microscopic, non-dipstick, detection of pyuria ≥10 wbc μl^{-1} has proved to be the best surrogate maker of urinary infection available, and superior to routine MSU culture [(2)]. This tempted antibiotic treatment, as an adjunct to antimuscarinics and bladder retraining, for patients with OAB symptoms and microscopic pyuria in fresh urine. Over 10 years (1993–2003), a treatment model evolved by trial and error using pyuria, symptom responses, and patient views in an approach akin to cultural Darwinism. A RCT is now appropriate but should be presaged by an open pilot to screen out a clinically insignificant efficacy signal.

Methods:

The model has been evaluated in an observational cohort study of 440 patients conducted from 2003 to 2010. Group 1 (n=147) had OAB & pyuria and were treated with antibiotics (primarily Nitrofurantoin or Cephalexin), additionally antimuscarinics and bladder retraining. Group 2 (n=212) had OAB, no pyuria and received only antimuscarinics and bladder retraining. Group 3 (n=81) had OAB and manifested pyuria late at which point antibiotics were commenced. Treatment response was monitored by urge scores, 24-h frequency and incontinence, and time taken to symptom resolution and pyuria clearance where appropriate.

Results:

There were 380 females and 60 males (mean age=54, sd=18) equally distributed between groups. At presentation 75% of group 1, 88% of group 2 and 85% of group 3 were MSU culture negative. There was a significant improvement in all symptoms and in all groups over the treatment period (F=59, p<.0001, see Fig. 1).

Group 3, prescribed antibiotics late, took significantly longer to recover (95%CI 198–321 days) (Fig. 2) compared to group 1 (95%CI 165–229 days) (Fig. 2). (F=8, p<.001, see Fig. 2). The late introduction of antibiotics was followed by significant symptom improvement (95% CI diff daily frequency=0.75 to 3.5 p=.002). Group 2, always without pyuria, recovered the fastest (95%CI 138–180 days) (Fig. 2).

Conclusion:

These data come from open observational work and must be viewed as provisional. The parallel course exhibited by groups 1 and 2 leaves the judgement on an antibiotic efficacy open, other than the clearance of pyuria in group1 and the shorter time-course of group 2. The effects in group 3, in response to later treatment, push the balance in the favour of antibiotic efficacy. The data are strong justification for a large-scale randomised, placebo controlled trial of antibiotic use in patients with OAB, pyuria, but negative urine culture.

References:

1. Neurourol.Urodyn., 2009, 8; 779, 780.
2. J.Urol., 17-3-2010, 183; 1843, 1847.

Figure 1

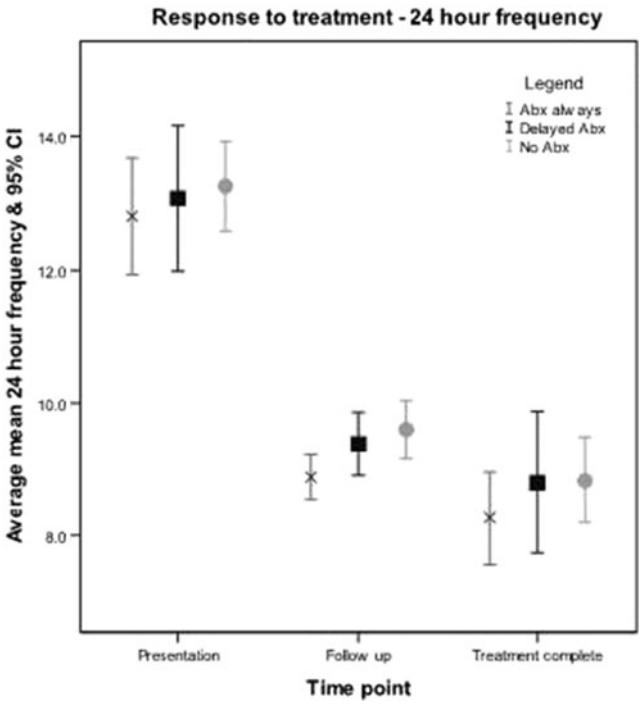
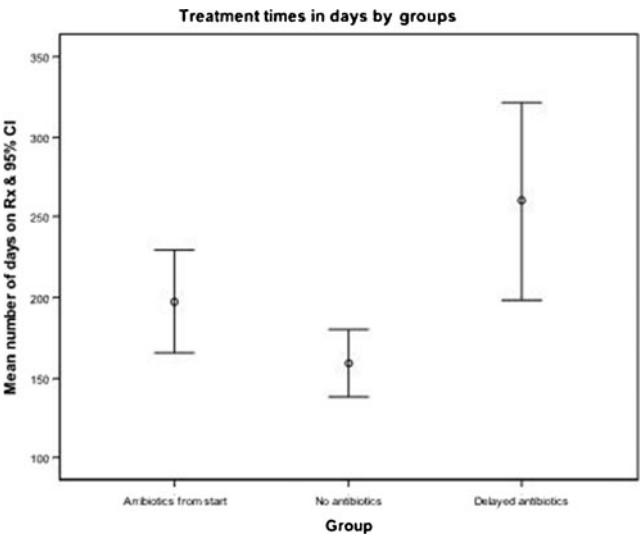


Figure 2



Presentation Number: 197

CAUGHT INFLAGRANTE—PATHOGENS FROM OAB PATIENTS OBSERVED AS THEY INVADE UROTHELIAL CELL LINES

R. K. KHASRIYA[1], S. ISMAIL[2], M. WILSON[2], J. MALONE-LEE[1]; [1]UCL, London, United Kingdom, [2]Eastman Dental Inst. UCL, London, United Kingdom.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:

This study was designed to test the hypothesis that microbes isolated from the urine of patients with overactive bladder (OAB) could be shown to be capable of invading and colonising a sterile cultured uroepithelial cell line. By contrast microbes obtained from asymptomatic controls would be less capable of invasion. The premise was that intracellular colonisation of uroepithelial cells by pathogens could be incriminated in the pathogenesis of OAB.

Background:

To propose that the urinary tract infection may play an important part in the aetiology of OAB, and that such infections miss detection by routine urine testing methods, is a bold claim. If correct it will greatly perturb our understanding of this unpleasant condition. It is entirely reasonable that such hypotheses should be submitted to rigorous repetitive testing and that any implied mechanisms be explored exhaustively.

Recent data have clearly implicated intracellular bacterial colonisation of the urothelial cells in the pathological mechanisms of acute urinary tract infection causing frequency dysuria. It has been discovered that in a murine model of UTI, populations of E. coli can persist in the bladder for months on end, during which time they exist as a quiescent reservoir of infection. This would be a most apt mechanism for achieving a chronic infection that was hard to detect, but nevertheless distress the bladder sufficiently to cause OAB symptoms.

Culture of the urinary cellular sediment in OAB patients has improved the ability to culture bacteria from patients with OAB symptoms and negative routine urine cultures (1). Comparisons with normal asymptomatic controls indicated that these isolates were part of a pathological process. If intracellular colonisation were an element in the disease, it would be unsurprising that culturing the concentrated cell sediment achieved a better means of isolating pathogens. However a key requirement would be to show that the isolates were capable of cell invasion.

Methods:

With ethical committee approval, we studied four bacterial isolates, previously isolated from patients presenting with symptoms of OAB and Lactobacillus.gaseri isolates, obtained from an asymptomatic control volunteers. A bladder epithelial cell line from a transitional cell carcinoma (EJ138) was grown to confluency in Eagles Minimal Essential Medium. Once confluent, the cells where infected with either Eschericia. coli, Enterococcus. faecalis, Streptococcus. angiosus, Proteus. mirabilis or Lactobacillus.gaseri with a multiplicity of infection of 100:1. After 2 h of incubation, the cultures were incubated with gentamicin 200 μg/ml to kill any extracellular bacteria. After a further 24 h, the epithelial cells were washed and lysed with Triton X 0.1%. Intracellular bacteria were enumerated by culture.

Results:

All bacteria cultivated from OAB patients showed invasion of bladder epithelium at 24 h. An increase in total bacterial count from zero can be seen after cell lyses (See figure). In contrast, the Lactobacillus.gaseri did not show invasion of the bladder epithelium.

Conclusions:

This assay confirms that uropathogenic bacteria isolated from patients with OAB symptoms have adapted for cell invasion. It is possible, that cell invasion and a reservoir of intracellular bacteria play a role in the persistence of OAB. It is important that other species additional to Eschericia. Coli have, for the first time, been implicated in this pathology.

References:

1. Neurourol.Urodyn., 2009; 8, 779–780.

Presentation Number: 198

A PROSPECTIVE COHORT STUDY OF THE IMPACT OF SURGICALLY-INDUCED WEIGHT LOSS ON LOWER URINARY TRACT SYMPTOMS

J. TAN-KIM, **C. L. GRIMES**, E. L. WHITCOMB, F. VAIDA, S. HORGAN, E. S. LUKACZ;
Univ. of California, San Diego, La Jolla, CA.

Consent obtained from patients: Yes
Level of support: Investigator initiated, no external funding
Work supported by industry: No

Objective:

This study aimed to determine the impact of surgically-induced weight loss on lower urinary tract symptoms (LUTS) including urinary frequency, nocturia, frequent urination, urgency and urge incontinence. We hypothesize that surgical weight loss results in a decrease in LUTS.

Background:

Epidemiologic studies support this relationship between obesity and urinary incontinence [1] and surgically induced

weight reduction has been associated with decreased severity of stress incontinence [2]. However, there are few studies which evaluate the impact of weight reduction on LUTS. The aim of our study was to examine the presence of LUTS before and after surgically-induced weight loss and determine odds of improvement by percent reduction in body mass index (BMI).

Method:

A sub-analysis of a prospective, observational cohort study of women undergoing laparoscopic adjustable gastric banding or sleeve gastrectomy for the treatment of obesity between 2007 and 2009 was performed. Subjects were given a validated questionnaire at baseline and 12-months status post surgery [3]. The following outcomes were explored: 1-urinary frequency (urinating>8 times per day); 2-nocturia (voiding≥2 times after bedtime); 3-frequent urination ("yes" to the question: "Do you experience frequent urination?"); 4-urgency ("yes" to: "Do you rush to the bathroom so that you will not have leakage of urine?"); and 5-urge urinary incontinence ("yes" to: "Do you experience urine leakage related to a feeling of urgency?") The difference between the symptoms of frequency and frequent urination was based on the subject's report of voiding more than 8 times per day vs. perception that they urinate too frequently. Subjects were categorized into 3 groups: new onset, no change, or resolution of LUTS. Ordinal regression models were used to determine the relationship between percent reduction in BMI and the 12-month change in LUTS. Adjustment for other covariates of interest including age, parity, menopausal status, hormone use, smoking, incontinence surgery, type 2 diabetes, depression, lung disease, hysterectomy, urinary tract infections, diuretic use, caffeine use, and baseline BMI were also considered.

Result:

Of the 98 women enrolled in the study 68 women had valid data at baseline and 12-month follow-up. They had a mean age of 43± 12 years and a median parity of 1[0–6]. Baseline BMI was 41± 6 kg/m^2. At 12-months the mean BMI was 34±6 kg/m^2, representing a 16% reduction from the baseline ($p<0.01$). There were no significant differences between those subjects included and those with incomplete data.

See Table 1 for LUTS changes from baseline. Resolution of frequent urination was significantly associated with percent BMI reduction, with a 2.6 odds of improvement for every 10% reduction in BMI after weight-loss surgery (95% CI: 1.21–5.23, $p<0.01$) (Fig. 1). While there was no significant association between change in urinary frequency or urgency with BMI reduction, there was a trend towards resolution of nocturia [OR 2.0 (95% CI: 0.95–4.00, $p=0.07$)] and urge incontinence [OR 2.1 (95% CI: 0.91–4.63, $p=0.08$)] with each 10% BMI reduction; these associations did not meet statistical significance.

In multivariable analyses no other variables were associated with change in symptoms for frequent urination.

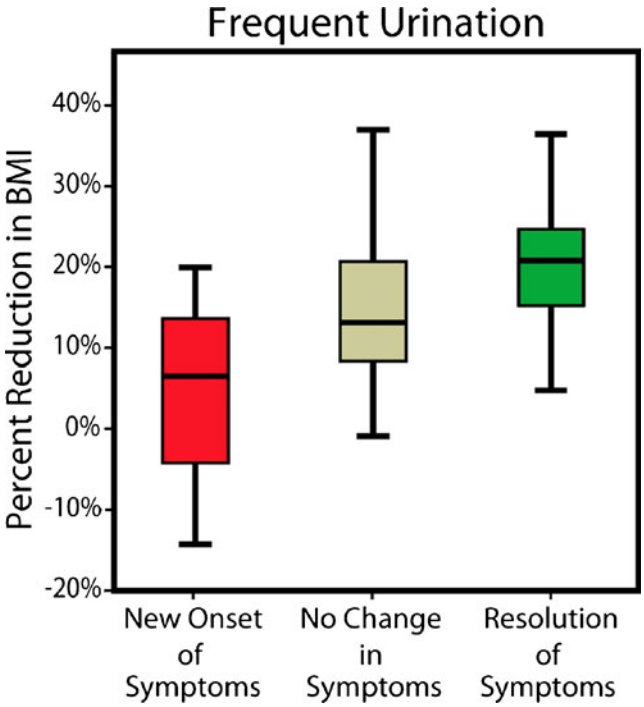
Conclusion:

Surgically-induced weight loss in the obese patient appears to have a significant impact on frequent urination with a 2.6 odds of resolution in symptoms for every 10% reduction in BMI and a trend towards decreased nocturia and urge incontinence. Larger studies with sufficient power are needed to confirm these results.

Table 1. Outcome Variables

	Change in symptoms from baseline to 12-months		**p-value**
Urinary Frequency $n=68$	New onset of symptoms	$n=10$ (14.9%)	0.32
	Symptoms unchanged	$n=51$ (76.1%)	
	Resolution of symptoms	***n*=6 (9%)**	
Nocturia $n=68$	New onset of symptoms	$n=1$ (1.5%)	**<0.01**
	Symptoms unchanged	$n=57$ (83.8%)	
	Resolution of symptoms	***n*=10 (14.7%)**	
Frequent Urination $n=68$	New onset of symptoms	$n=4$ (5.9%)	0.11
	Symptoms unchanged	$n=54$ (79.4%)	
	Resolution of symptoms	***n*=10 (14.7%)**	
Urgency $n=67$	New onset of symptoms	$n=1$ (1.5%)	**0.02**
	Symptoms unchanged	$n=56$ (86.2%)	
	Resolution of symptoms	***n*=8 (12.3%)**	
Urge Incontinence $n=68$	New onset of symptoms	$n=1$ (1.5%)	**0.03**
	Symptoms unchanged	$n=60$ (88.2%)	
	Resolution of symptoms	***n*=7 (10.3%)**	

Reference:
1. JAMA 295(13): 1549–55
2. Ob Gynecol 110(5): 1034–40
3. Int Urogyn J Pelvic Floor Dysfunct 16(4): 272–84



Presentation Number: 199

EVALUATION OF THE SUMIT TRIAL: INSIGHTS INTO PERCUTANEOUS TIBIAL NERVE STIMULATION

P. SAND[1], N. SHORE[2], D. ELSER[3], K. PETERS[4];
[1]Evanston Continence Ctr., Evanston, IL, [2]Carolina Urologic Res. Ctr., Myrtle Beach, SC, [3]Illinois Urogynecology LTD., Oak Lawn, IL, [4]Beaumont Hosp., Royal Oak, MI.

Consent obtained from patients: Yes
Level of support: Industry-initiated, full sponsorship
Work supported by industry: Yes

Objective:
The objective of this review is to evaluate the clinical outcomes of percutaneous tibial nerve stimulation (PTNS) in the 23-center SUmiT Trial.

Background:
Overactive bladder syndrome (OAB) affects the lives of millions of people. Neuromodulation therapy uses electrical stimulation to target specific nerves in the sacral plexus that control bladder function. Urgent® PC PTNS targets the sacral plexus from an accessible, minimally invasive entry point into the nervous system -the posterior tibial nerve.

Methods:
220 subjects were randomized 1:1 to PTNS or validated sham as part of their participation in the SUmiT Trial. Subjects received 12 PTNS or sham treatments during 30-min weekly sessions. Subjects completed questionnaires and 3-day voiding diaries during their participation.

Results:
In an intent-to-treat analysis, the Global Response Assessment (GRA) found 54.5% were responders (moderately or markedly improved) in the PTNS group compared to 20.9% in the sham group ($p<0.001$). All GRA outcomes were statistically significant at 13 weeks compared to baseline, but outcomes were not significant at 7 weeks (Table). Similarly, OAB-q quality of life questionnaires were significantly improved at 13 weeks, but not at 7 weeks between treatment groups. GRA outcomes at 13 weeks, in those previously treated with an OAB medication were higher than those naïve to pharmacotherapy, 62.9% compared to 48.5% for the PTNS

GRA Outcome	Group	7 weeks	p-value	13 weeks	p-value
Overall Bladder symptoms	PTNS	28/105 (26.7%)	0.07	60/103 (58.3%)	<0.001
	Sham	17/107 (15.9%)		23/105 (21.9%)	
Urgency	PTNS	23/105 (21.9%)	0.61	44/103 (42.7%)	0.003
	Sham	29/107 (18.7%)		24/103 (22.9%)	
Frequency	PTNS	29/105 (27.6%)	0.10	49/103 (47.6%)	<0.001
	Sham	19/107 (17.8%)		23/105 (21.9%)	
Urge Incontinence	PTNS	14/103 (13.6%)	0.84	39/103 (37.9%)	0.02
	Sham	13/106 (12.3%)		23/104 (22.1%)	

arm. When results were stratified by age, <65 years vs. ≥65 years, no significant difference in efficacy was found in either study arm. The mean age was 62.5 years and 60.2 years for PTNS and sham, respectively. No significant changes in sexual function indices were reported by either study arm or gender (174 females, 46 males). No serious treatment-related adverse events were reported.

Conclusions:

Based upon the GRA and OAB-q quality of life response outcomes at 7 and 13 weeks, 12 weekly sessions of PTNS treatments are needed for the treatment to be efficacious for those suffering with OAB syndrome. PTNS therapy is an efficacious treatment for those suffering with OAB syndrome, regardless of age.